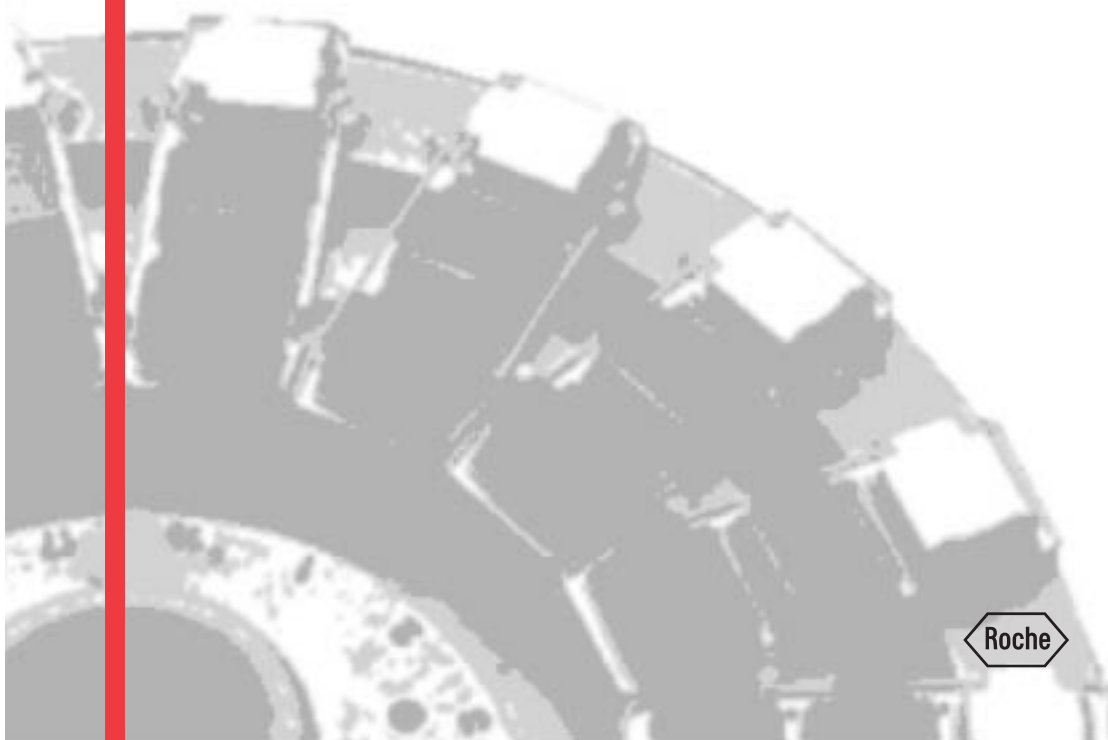


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## Software Guide

### *Roche Diagnostics Elecsys® 2010 System Operator's Manual*



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# Software Guide

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## Chapter 1

# Software Basics

## 1.1 Software Basics

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### Introduction

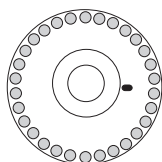
The Software Guide outlines the software screens on your analyzer. An example and a brief description of each screen are included. Before discussing specific screens and how to use them, some general instructions concerning software basics are necessary.



*The screen representations shown in this chapter and throughout this manual are for illustrative purposes only. The data shown may not reflect the same setup as your analyzer.*

### Disk and Rack Identifiers

The 2010 software screens are sometimes different depending upon whether you have a disk or a rack analyzer. All fields and buttons on the screen are described in the following sections. However, those fields/buttons that are specific to a system have a corresponding graphic next to it in the margin. See below.



Disk



Rack

### Touchscreen

Your Elecsys 2010 analyzer is equipped with a touchscreen system. In a touchscreen system, you touch what you see on the screen. Many of the items within the software can be accessed using the touchscreen. Touch the screen item desired (screen button, field, etc.) to quickly complete your task. When touching the screen, be sure to "touch," not "press." A touch should be of short duration.

## 1.1 Software Basics

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### Buttons and Tabs

*Buttons* and *tabs* are used throughout the software. Buttons can be used to access a pop-up window, display a new screen or to initiate an immediate action, such as starting a reagent scan. When in a screen, they are referred to as “screen buttons.” In a pop-up window, they are referred to as “window buttons.”

Tabs are used to access one of the six “folders” (i.e., INVENTORY, ORDERS, RESULTS, QC, STATUS and UTIL). Each folder consists of one or more screens, and/or pop-up windows. Buttons and tabs can change color depending upon whether or not they are selected. When you see a reference to a button or tab, the text in the manual looks as follows:

Touch the  button. Or Touch .

This is your cue to touch a button or tab on the touchscreen.



*Buttons and tabs are always “touched.”*

### Data Fields and Data Entry Fields

The software contains two types of fields. *Data fields* display information only and have no user access. *Data entry fields* are used to enter information. When you touch an empty data entry field, the field is highlighted. When you see a reference to either kind of field on a screen, the text in the manual changes to a different type as follows:

Enter a patient sample ID in the `Sample ID` field.

### Keys

*Keys* are used to enter, select or confirm information. When you need to complete an action on the keyboard, you are asked to press a key on the keyboard. When you see a reference to a key on the keyboard, the text in the manual changes to visually reflect the appropriate key as follows:

Press .

This is your cue to press a key on the keyboard.

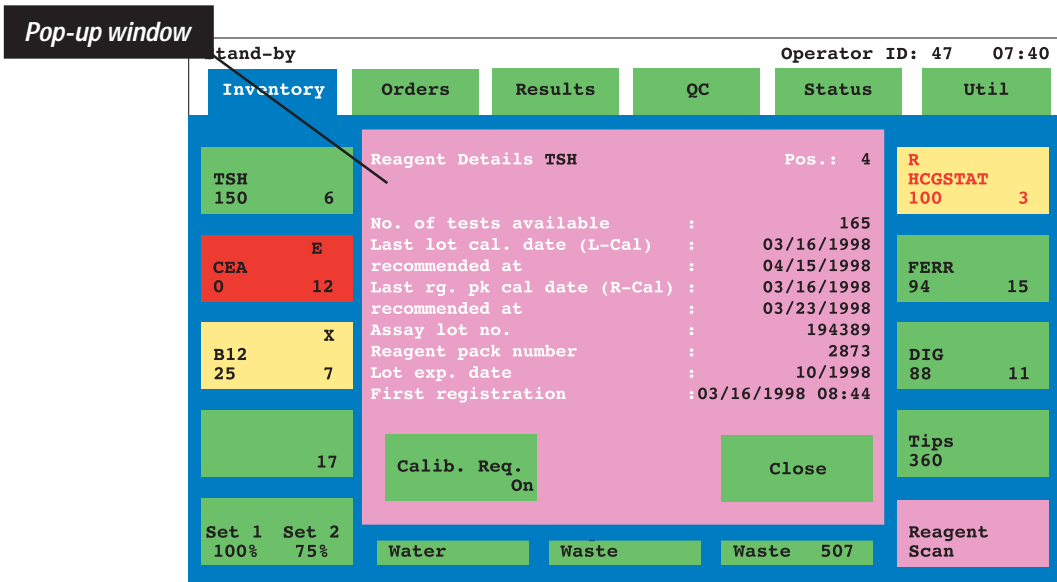


*Keys are always “pressed.”*

# 1.1 Software Basics

## Pop-up Windows

Windows contain additional information that “pop up” within existing screens. A window may appear as a result of touching a button on a screen.



## Screen and Pop-up Window References

In this manual, screens are referred to in all capital letters (e.g., INVENTORY screen). Pop-up window references appear in mixed case letters enclosed in single quotes (e.g., 'Reagent Details' pop-up window).

## 1.2 Software Basics, Keyboard Layout

### Keyboard Layout and Operation

The keyboard on the Elecsys 2010 analyzer is composed of global action keys, navigation and numeric keys.



2010 keyboard

### Global Action Keys



Use this key to enter the STAT mode and process STAT samples.



Use this key to place the instrument into operation.



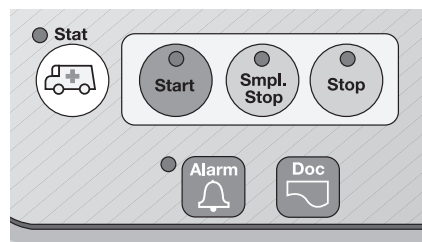
Use this key to stop sampling or to prevent the analyzer from going into Stand-by. Test processing continues for patient samples already pipetted.



Use this key to stop test processing at the end of the current instrument cycle. This key puts the analyzer into Stand-by. All samples in process need to be repeated.



Use this key to access the 'Alarm' pop-up window and to clear the alarm from the status line. When an alarm occurs, the status line of the touchscreen turns a different color and a buzzer sounds. Refer to Chapter 3, Instrument Alarms – *User's Guide*, for details on the alarm key and how to change its setup.



Global action keys

## 1.2 Software Basics, Keyboard Layout

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Use this key to print reports or to manually upload patient results. Pressing the key a second time stops the analyzer from sending more data to the printer.

### Navigation Keys



Prev

Use this key to scroll to the previous page or data record.



Next

Use this key to scroll to the next page or data record.



Navigation keys

### Numeric Keys

These are the numeric keys. They are used to enter numeric values.




Use this key to confirm entries in fields.



Use this key to clear and delete data from fields.



Use this key to cancel the last sample programmed on the ORDERS screen. This key only works in conjunction with .



Numeric keys



## 1.3 Software Basics, Screen Configuration

### Screen Configuration

The software is easy to use and navigate. Refer to the screen below.

The screenshot displays the software's main interface. At the top is a status line with the text 'Stand-by' on the left and 'Operator ID: 47 07:40' on the right. Below this is a row of six tabs: 'Inventory', 'Orders', 'Results', 'QC', 'Status', and 'Util'. The main area consists of a grid of buttons. Each button contains text such as 'TSH 150 6', 'CEA 0 12', 'B12 25 7', 'Set 1 100% Set 2 75%', 'C T4 180 1', 'AFP 70 5', 'P-B12 25 8', 'Distilled Water', 'T3 80 4', 'PSA 84 13', 'FOL 90 9', 'Liqud Waste', 'RC HCGSTAT 100 2', 'FERR 94 14', 'DIG 18 10', 'Solid Waste 507', 'R HCGSTAT 100 3', 'FERR 94 15', 'DIG 88 11', 'Tips 360', and 'Reagent Scan'. Callouts from the left point to the 'Status line', a 'Tab or folder' (the tabs row), and a 'Button' (one of the main grid buttons).

### Status Line

The status line displays the operator ID, system status and actual time. This line changes colors when an alarm is present. The operator ID is the identification number of the last operator to log onto the system. The system status displays the current operating conditions. A listing of system status conditions can be found in Chapter 3, Mechanical Theory – *Reference Guide*.

## 1.3 Software Basics, Screen Configuration

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### Screen Buttons

The main menu of screen buttons are displayed as a series of “file folders.” Each “folder” can be accessed by touching the corresponding tab.

#### Inventory

This screen is used to track inventory for reagents and consumables, and to perform a reagent scan.

#### Orders

This screen is used for making manual sample and test requests and printing a work list.

#### Results

This screen is used for viewing, blocking, filtering, releasing, printing or uploading test results and deleting documented samples.

#### QC

This screen is used to monitor and track QC values.

#### Status

This screen is used for on-screen sample tracking, operator ID entry, scanning samples on the disk system and deleting open requisitions.

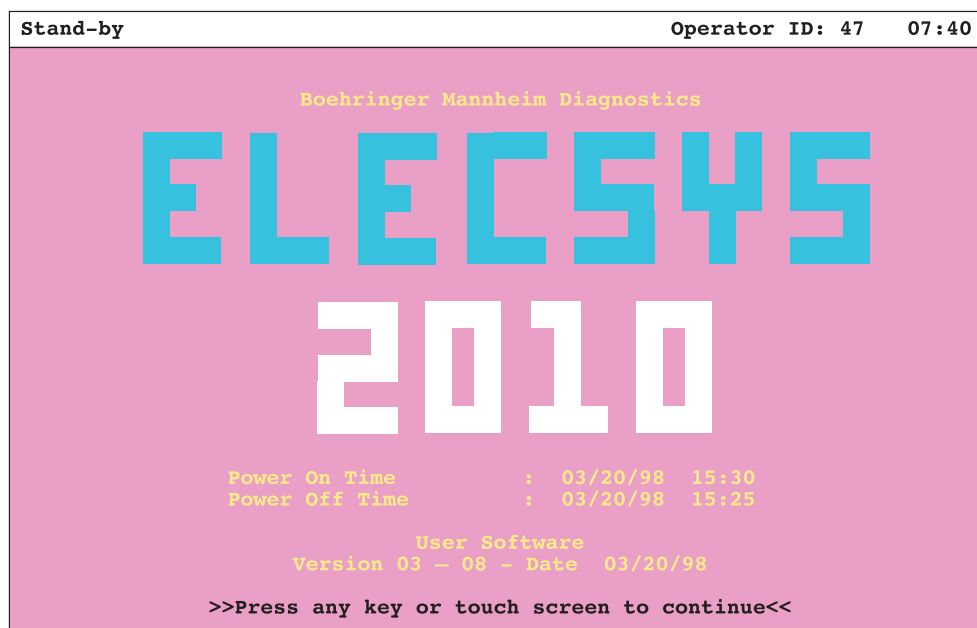
#### Util

The UTIL screen is used to perform administrative, maintenance and service functions.

## 1.3 Software Basics, Screen Configuration

### Software Access

Before working with the software, power ON the Elecsys 2010 analyzer. If the analyzer is powered ON at the circuit breaker, then the introductory screen appears soon after. (The operation switch must also be on for this screen to appear.)



Introductory screen

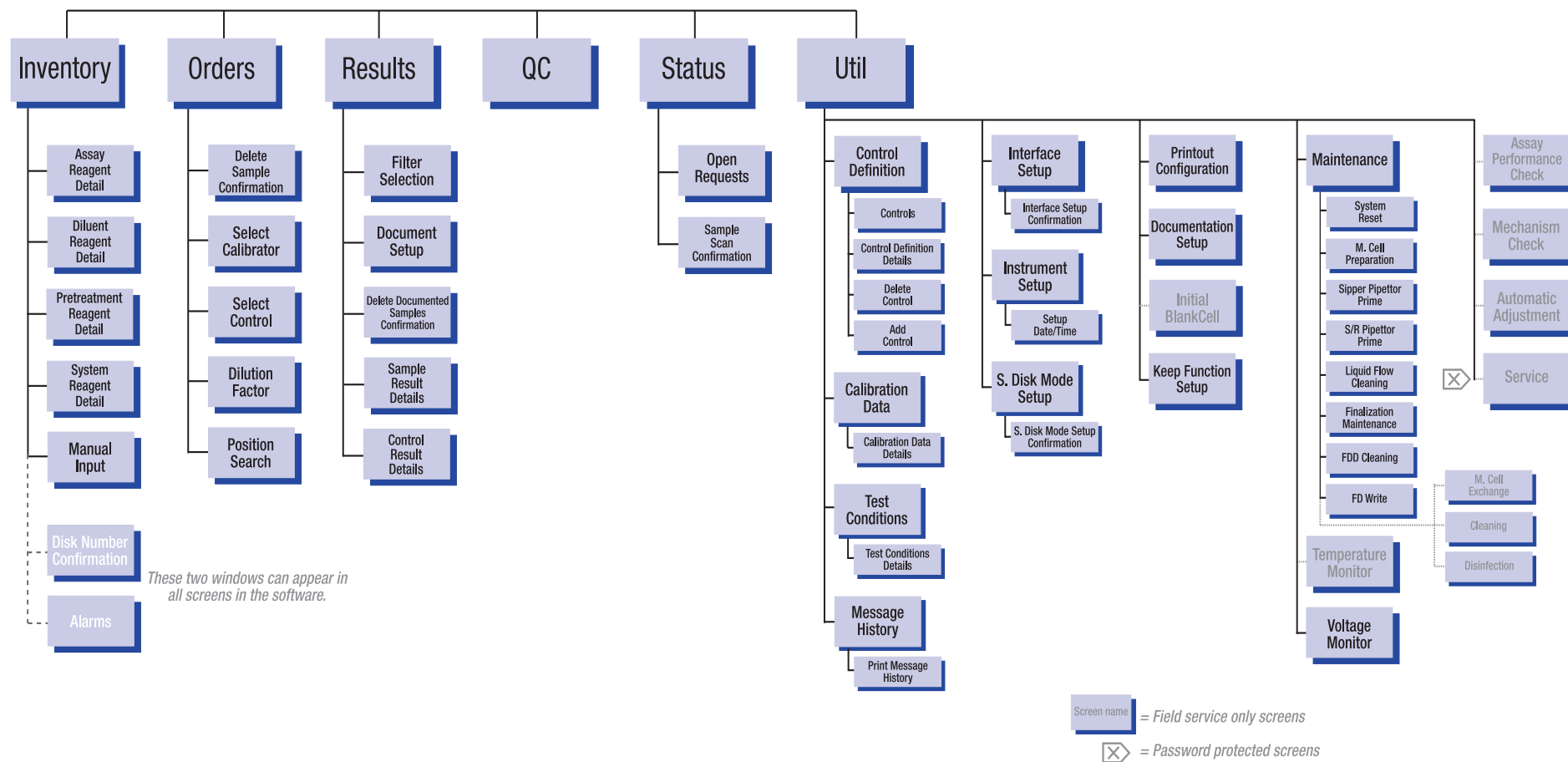
You simply need to follow the directions on the screen. Either press any key on the keyboard or touch the screen to enter the INVENTORY screen.

Normally, the analyzer is powered ON or OFF at the operation ON/OFF switch. When you power the operation switch ON, the software accesses the last screen the system was in when the analyzer was powered OFF. Touch Inventory to access the INVENTORY screen and check system inventory.

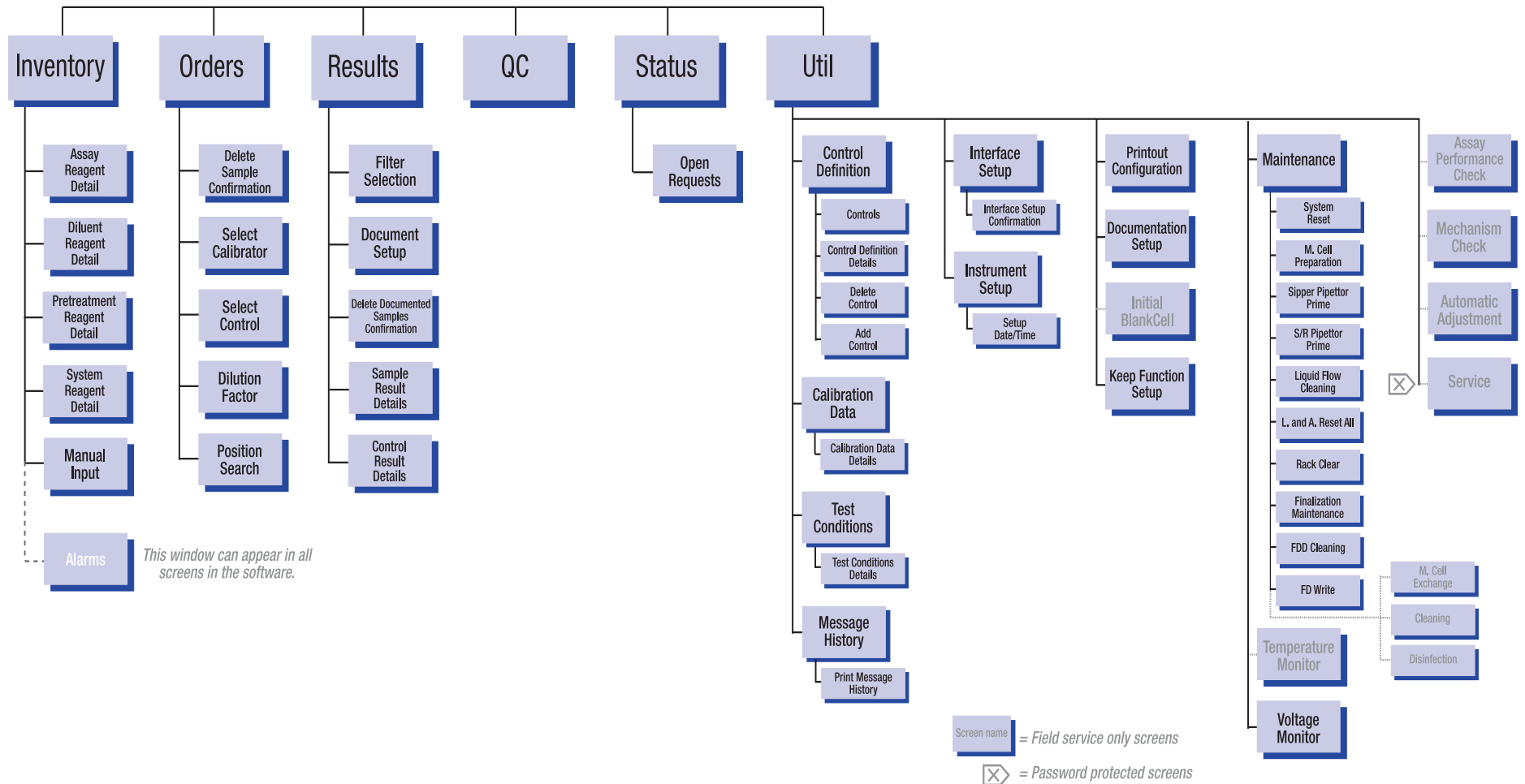
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## Notes

## 1.4 Software Basics, Software Flowchart – Disk System



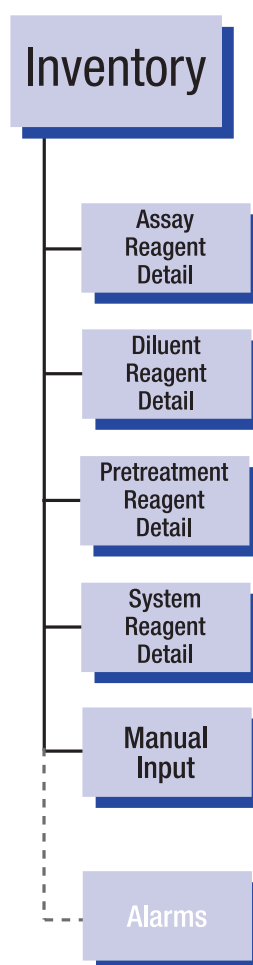
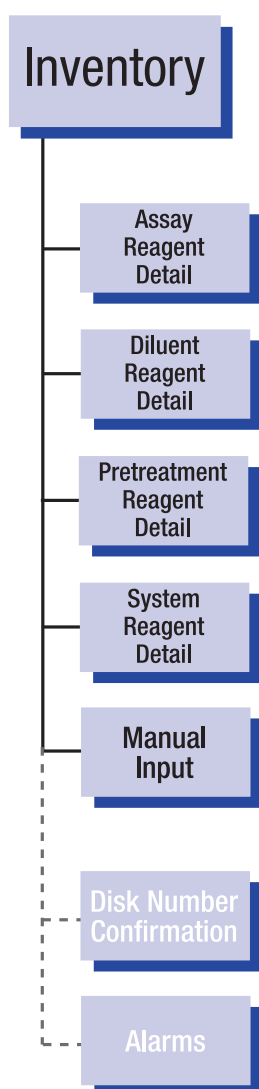
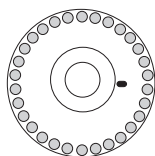
## 1.5 Software Basics, Software Flowchart – Rack System



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## Chapter 2

# Inventory Screen



## 2.1 INVENTORY Screen

### Introduction

The INVENTORY screen displays current information on the reagent packs, tips, cups, etc., that are set up on the analyzer. Inventory on the analyzer is updated during operation or by a reagent scan. You can load 15 different assays, diluent and/or pretreatment in 18 reagent positions. You can load a maximum of eight diluent reagent packs.

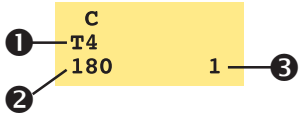
### INVENTORY Screen

An example of the INVENTORY screen is shown below.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Util
TSH 150 6	C T4 180 1	T3 80 4	RC HCGSTAT 100 2	R HCGSTAT 100 3	
CEA 0 12	AFP 70 5	PSA 84 13	FERR 94 14	FERR 94 15	
B12 25 7	P-B12 25 8	FOL 90 9	DIG 18 10	DIG 88 11	
		Dil Uni 18 16	Cups 100	Tips 360	
Set 1 Set 2 100% 75%	Distilled Water	Liquid Waste	Solid Waste 507	Reagent Scan	

### Screen Buttons

The following is a description of the buttons on the INVENTORY screen.



There are 18 test code buttons indicating individual reagent packs on the reagent disk. The middle line on the button represents the test code (❶). The bottom left number indicates the reagent remaining in the pack in terms of number of tests (❷). The bottom right number indicates the reagent's position number on the reagent disk (❸). A maximum of 15 different assays can be loaded at one time on the reagent disk.



## 2.1 INVENTORY Screen

The buttons are listed in test number order. The test number is encoded in the reagent bar code; however it can be changed in the 'Test Conditions Details' pop-up window (UTIL folder). Changing the test number allows you to see assays on the reagent disk grouped together as you desire. For example, if all thyroid assays are assigned sequential test numbers, they will appear together on the INVENTORY screen, even though actual reagent packs are randomly placed on the reagent disk.



*If you elect to change your test number in this window, be aware that the test number utilized by the host interface remains the same as the one encoded in the reagent bar code (i.e., the number that appears in this window when your software was loaded). If your analyzer is interfaced, we recommend that you do not change the test number.*

A green test button means that a valid calibration exists for the assay. Detailed information for an individual assay reagent pack is displayed in the 'Reagent Details' pop-up window by touching the corresponding test button.

<b>TSH</b>	
<b>150</b>	<b>6</b>

A yellow test button with an "RC" and red text means an L-Cal is requested by the system. If there is more than one reagent pack of a single lot on the reagent disk, only the reagent pack to be calibrated according to automatic calibration (i.e., calibration by loading) gets "RC." This calibration can be changed in the assay 'Reagent Details' pop-up window. If an "X" also appears in the upper right corner of this button, the reagent is expired and the calibration generated by the analyzer can only be a reagent pack calibration (R-Cal).

<b>RC</b>	
<b>RCGSTAT</b>	
<b>200</b>	<b>2</b>

A yellow test button with an "R" and red text means this is a new reagent pack with no L-Cal available. Another reagent pack for the assay was prioritized by the system for L-Cal or you manually deselected the L-Cal (the test button previously was "RC").

<b>R</b>	
<b>RCGSTAT</b>	
<b>200</b>	<b>3</b>

A yellow test button with a "C" and black text means the calibration for the assay was manually requested in 'Reagent Details' or the daily calibration expired. (Daily calibration applies to qualitative assays only.)

<b>C</b>	
<b>T4</b>	
<b>180</b>	<b>1</b>

A yellow test button with a "T" and black text means the minimum available tests threshold for the assay was reached. The threshold is defined in the 'Test Conditions Details' pop-up window/TEST CONDITIONS screen (UTIL folder).

<b>T</b>	
<b>DIG</b>	
<b>18</b>	<b>10</b>

A yellow test button with an "X" and black text means the reagent pack is expired. Results are flagged with the data alarm 52, "Expired reagent pack."

<b>X</b>	
<b>B12</b>	
<b>25</b>	<b>7</b>

## 2.1 INVENTORY Screen

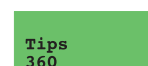
A red test button with an “E” and black text means that the reagent pack is empty.



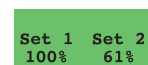
A red test button with an “N” and black text means the test cannot be calibrated; the corresponding pretreatment reagent pack is missing from the reagent disk.



The number below “Cups” on the assay cups button indicates the remainder of available cups on the analyzer. The button changes color from green to yellow when the inventory is < 60 (i.e., one tray left). The button changes from yellow to red when the inventory reaches 0 (zero).



The number below “Tips” on the assay tips button indicates the remainder of available disposable tips on the analyzer. The button changes color from green to yellow when the inventory is < 120 (i.e., one tray left). The button changes from yellow to red when the inventory reaches 0 (zero).



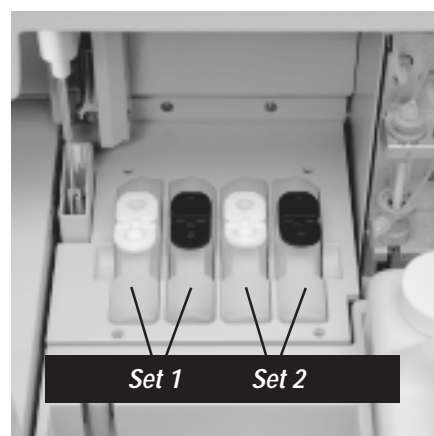
Touching this button accesses the ‘System Reagent Details’ pop-up window.

The numbers below the letters “PC” and “CC” indicate the remaining percentage of the system reagents, ProCell and CleanCell. The button is green if the percentage of Set 1 and Set 2 is > 30%. The button is yellow if the total of Set 1 and Set 2 are > 0 and < 30%. If both sets are 0 (zero) the button turns red.

Provide adequate time to let the new reagents reach 28 °C. There is a sensor in the system reagent compartment that detects the presence or absence of a bottle set. After a new set is detected, the analyzer does not use the new bottle set for 15 minutes. Therefore, check your system reagents first when examining inventory prior to operation.



*Set 1 occupies positions 1 and 2. Set 2 occupies positions 3 and 4, and is the first set used when starting from Stand-by.*



## 2.1 INVENTORY Screen

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Distilled  
Water

The color of this button changes from green to red if the distilled water container is empty. Replenish the distilled water container when this button turns red.

Liquid  
Waste

The color of this button changes from green to red when the waste container becomes full. When this button turns red, discard the waste in the liquid waste container.

During operation, if an alarm condition for the distilled water or liquid waste occurs, a P. Stop alarm is issued. Tests currently in process are completed. However, if the condition exists when you start operation from Stand-by, a Stop alarm is issued.

Solid  
Waste 507

The button displays the total number of cups/tips used and changes from green to red if more than 800 cups/tips are counted.

Reagent  
Scan

Touching this button initiates a scan of the reagent pack bar code labels on the reagent disk. In addition, the gripper checks the assay cups and tips, and the sipper probe checks the levels of ProCell and CleanCell. The word "Scanning" flashes on the status line while the scan is active. When the scan is complete, the INVENTORY screen updates all the test buttons, cups, tips and ProCell/CleanCell. A reagent scan can only be initiated from Stand-by.



*Make sure that all ProCell and CleanCell lids are open when you initiate a reagent scan.*

### Keyboard Functions

The following is a description of the keys that are active while in the INVENTORY screen.



Press this key to obtain an inventory report for the analyzer. Pressing the key a second time stops the analyzer from sending more data to the printer. Printing may not stop immediately.

## 2.2 'Reagent Details' Pop-up Window

### Introduction

When you touch a test button that shows reagent information, the 'Reagent Details' pop-up window appears, displaying detailed information on the assay's reagent pack. 'Reagent Details' windows differ for an assay or diluent reagents.

### 'Reagent Details' Pop-up Window

An example of the 'Reagent Details' pop-up window is shown below.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Util
<b>TSH</b> 150 6	<b>Reagent Details TSH</b> Pos.: 4				<b>R</b> HCGSTAT 100 3
<b>CEA</b> 0 12	No. of tests available : 165				<b>FERR</b> 94 15
<b>B12</b> 25 7	Last lot cal. date (L-Cal) : 03/16/1998				<b>DIG</b> 88 11
	recommended at : 04/15/1998				<b>Tips</b> 360
	Last rg. pk cal date (R-Cal) : 03/16/1998				<b>Reagent Scan</b>
	recommended at : 03/23/1998				
	Assay lot no. : 194389				
	Reagent pack number : 2873				
	Lot exp. date : 10/1998				
	First registration : 03/16/1998 08:44				
	<b>Calib. Req.</b> On				
	<b>Close</b>				
Set 1 Set 2 100% 75%	Water	Waste	Waste	507	

### Data Fields

The following is a description of the fields on the 'Reagent Details' pop-up window. These fields have no user access; they are for display only.

#### Pos.

The reagent pack position number on the reagent disk.

#### No. of tests available

The amount of remaining reagent in terms of the number of possible tests.

#### Last lot cal. date (L-Cal)

The date of the last valid lot calibration for the displayed lot number.

#### recommended at

The date at which the next L-Cal is recommended. This date should primarily be used by high volume reagent users (i.e., the reagent pack is used in less than 7 days.)

## 2.2 'Reagent Details' Pop-up Window

### **Last rg. pk cal. date (R-Cal)**

The date of the last valid reagent pack calibration for the displayed lot number.

### **recommended at**

The date at which the next R-Cal is recommended. This date should primarily be used by lower volume reagent users (i.e., the reagent pack is **not** used within 7 days.)

### **Assay lot no.**

The lot number of the reagent pack. The lot number is found on the reagent bar code label. Refer to **1** in the graphic on the right.

### **Reagent pack number**

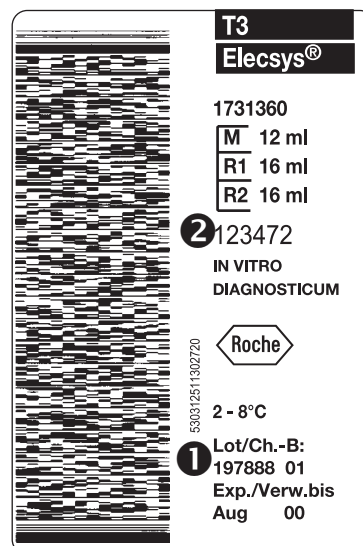
The unique number on the reagent bar code label that identifies each reagent pack. Refer to **2** in the graphic on the right.

### **Lot exp. date**

The lot's expiration date.

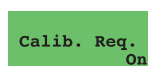
### **First registration**

The date and time the reagent pack was first registered (i.e., successfully scanned) by the software.



### **Window Buttons**

The following is a description of the buttons found on the 'Reagent Details' pop-up window.



Use this button to manually request a calibration on the reagent pack or to deselect an automatically requested calibration. Touch the button to toggle from "Off" to "On." This feature is convenient for multiple reagent packs of the same assay on the analyzer at the same time.



Touch this button to close the 'Reagent Details' pop-up window and return to the INVENTORY screen.

## 2.3 'Reagent Details' Pop-up Window for Diluent

### Introduction

When you touch the test button for diluent, a 'Reagent Details' pop-up window specific for diluent appears.

### 'Reagent Details' Pop-up Window for Diluent

An example of the 'Reagent Details' pop-up window for diluent is shown below.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Util
TSH 150 6	<div>Reagent Details Dil Uni Pos.: 16</div> <div>No. of milliliters available : 18</div> <div>Diluent lot no. : 194408</div> <div>Reagent pack number : 4706</div> <div>Lot exp. date : 07/1998</div> <div>First registration : 03/16/1998 08:44</div> <div>Close</div>				R HCGSTAT 100 3
CEA 0 12					FERR 94 15
B12 25 7					DIG 88 11
17					Tips 360
Set 1 Set 2 100% 75%					Reagent Scan
Water		Waste	Waste 507		

### Data Fields

The following is a description of the fields on the diluent 'Reagent Details' pop-up window. These fields have no user access; they are for display only.

#### Pos.

The diluent reagent pack position number on the reagent disk.

#### No. of milliliters available

The volume of diluent remaining in the diluent reagent pack.

#### Diluent lot no.

The diluent lot number.

#### Reagent pack number

The unique number on the reagent bar code label that identifies each reagent pack.

## 2.3 'Reagent Details' Pop-up Window for Diluent

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### **Lot exp. date**

The diluent lot expiration date.

### **First registration**

The date and time the diluent reagent pack was first registered (i.e., successfully scanned) by the software.

### **Window Buttons**

The following is a description of the buttons found on the diluent 'Reagent Details' pop-up window.

A green rectangular button with the word "Close" in white text.

Touch this button to close the diluent 'Reagent Details' pop-up window and return to the INVENTORY screen.

## 2.4 'Reagent Details' Pop-up Window for Pretreatment

### Introduction

When you touch the test button for pretreatment, a 'Reagent Details' pop-up window specific for pretreatment appears.

### 'Reagent Details' Pop-up Window for Pretreatment

An example of the 'Reagent Details' pop-up window for pretreatment is shown below.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Util
<b>TSH</b> 150 6	<b>Reagent Details P-B12</b>			Pos.: 8	<b>R</b> <b>HCGSTAT</b> 100 3
<b>CEA</b> 0 12	No. of tests available :			25	<b>FERR</b> 94 15
<b>B12</b> 25 7	Pretreatment lot no. :			674804	<b>DIG</b> 88 11
	Reagent pack number :			91	<b>Tips</b> 360
	Lot exp. date :			02/1998	<b>Reagent Scan</b>
	First registration :			03/16/1998 08:44	
	<b>Close</b>				
Set 1 Set 2 100% 75%	Water	Waste	Waste	507	

### Data Fields

The following is a description of the fields on the pretreatment 'Reagent Details' pop-up window. These fields have no user access; they are for display only.

#### Pos.

The pretreatment reagent pack position number on the reagent disk.

#### No. of tests available

The amount of remaining reagent in terms of the number of possible tests.

#### Pretreatment lot no.

The lot number of the pretreatment reagent pack.

#### Reagent pack number

The unique number on the reagent bar code label that identifies each reagent pack.



## 2.4 'Reagent Details' Pop-up Window for Pretreatment

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### **Lot exp. date**

The expiration date of the lot of pretreatment reagent.

### **First registration**

The date and time the pretreatment reagent pack was first registered (i.e., successfully scanned) by the software.

### **Window Buttons**

The following is a description of the buttons found on the pretreatment 'Reagent Details' pop-up window.

A green rectangular button with the word "Close" in white text.

Touch this button to close the pretreatment 'Reagent Details' pop-up window and return to the INVENTORY screen.

## 2.5 'System Reagent Details' Pop-up Window

### Introduction

When you touch the test button for system reagents, the 'System Reagent Details' pop-up window appears. The window tells you the percentage of ProCell and CleanCell in each set, as well as the lot number of ProCell in each set.

### 'System Reagent Details' Pop-up Window

An example of the 'System Reagent Details' pop-up window is shown below.

Stand-by Operator ID: 47 07:40

Inventory Orders Results QC Status Util

**System Reagent Details**

Set 1		Set 2	
PC	CC	PC	CC
100%	100%	75%	78%
Lot No. of PC		Lot No. of PC	
67400701		67400701	

OK Cancel

Set 1 Set 2  
100% 75%

Distilled Water Liquid Waste Solid Waste 507

Reagent Scan

### Data Entry Fields

The following is a description of the fields on the 'System Reagent Details' pop-up window. Not all fields allow data entry. Those that can be accessed are highlighted when touched.

#### Set 1/Set 2 PC

The percentage of ProCell in Set 1 or Set 2.

#### Set 1/Set 2 CC

The percentage of CleanCell in Set 1 or Set 2.

#### Lot No. of PC

Touch this field to enter the lot number of ProCell reagent. Press  to confirm the entry. The default lot number is 0 (zero).

## 2.5 'System Reagent Details' Pop-up Window

---

### Window Buttons

The following is a description of the buttons found on the 'System Reagent Details' pop-up window.



Touch this button to accept the data entered in the field. The window closes and returns to the INVENTORY screen.



Pressing this button does not accept the data entered in the field. The window closes and returns to the INVENTORY screen.

### Keyboard Functions

The following is a description of the keys that are active on the 'System Reagent Details' pop-up window.



Confirms an entry in the Lot No. of PC field.

## 2.6 'Manual Input' Pop-up Window

### Introduction

In the rare instance when a reagent bar code label cannot be read by the bar code reader, you can enter the reagent bar code number manually to update the inventory on the analyzer. Touching a blank test button on the INVENTORY screen accesses the 'Manual Input' pop-up window. When the appropriate information is entered and confirmed, the reagent pack information appears on the button that you touched.



*Make sure that you place the reagent pack in the correct position on the reagent disk (i.e., the position corresponding to the test button touched).*

You can only use this function if the lot number has previously been used on the analyzer. Should a bar code not read for a new assay, try a different reagent pack and manually enter this pack at a later date.



*If you enter a bottle number and this lot number was not previously registered, the **OK** and **Cancel** buttons are not active.*

A manually entered reagent pack can be overwritten by placing another reagent pack in the same position as that of the manually entered reagent pack and performing a reagent scan.

This pop-up window can be used for assay reagents or diluent.

### 'Manual Input' Pop-up Window

An example of the 'Manual Input' pop-up window is shown below.

Stand-by				Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Util
TSH 150 6	C T4 180 1	T3	RC HCGSTAT	R HCGSTAT 100 3	
CEA 0 12	AFP 70 5	Manual Input Pos.: 17 Rgt. BC no. : 0000184689782464 Lot no. : 193398 Test code : TNTSTAT OK Cancel		FERR 94 15	
B12 25 7	P-B12 25 8			DIG 88 11	
				Tips 360	
Set 1 Set 2 100% 75%	Distilled Water	Liquid Waste	Solid Waste 507	Reagent Scan	

## 2.6 'Manual Input' Pop-up Window

### Data Entry Fields

The following is a description of the entry fields in the 'Manual Input' pop-up window. Not all fields allow data entry. Those that can be accessed are highlighted when touched.

#### Pos.

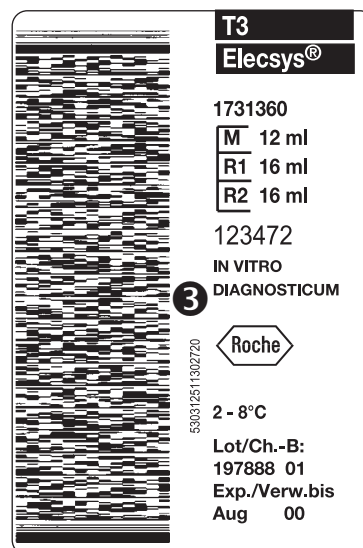
The position on the reagent disk that the manually entered reagent pack will occupy. There is no user access to this field.

#### Rgt. BC no.

The 15-digit human readable bar code number found on the reagent bar code label. Refer to **3** in the graphic on the right. Touching the field activates it for data entry. Touching the field a second time clears previously entered data.



*This field actually holds 16 digits. After confirming the 15-digit bar code number, the software adds a leading 0 (zero) to the number displayed.*



#### Lot no.

The lot number of the reagent pack, found on the reagent bar code label. This number appears automatically after the bar code number is entered and confirmed. There is no user access.

#### Test code

The assay's test code. The test code appears automatically after the bar code number is entered and confirmed. There is no user access.

### Window Buttons

The following is a description of the buttons that appear on the 'Manual Input' pop-up window.



Pressing this button accepts the data entered in the field. The window closes and returns to the INVENTORY screen.



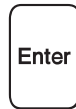
Pressing this button does not accept the data entered in the field. The window closes and returns to the INVENTORY screen.

## 2.6 'Manual Input' Pop-up Window

---

### Keyboard Functions

The following is a description of the keys that are active while in the 'Manual Input' pop-up window.



Press this key to confirm data entry.




Press this key to clear data from the Rgt. pack no. field that has not been confirmed by pressing



## 2.7 Disk Number 'Confirmation' Pop-up Window

### Introduction

Whenever you start operation on the Elecsys 2010 disk system and you are operating in the multiple sample disk mode, you are asked to confirm what disk is on the analyzer. This way you can verify that the analyzer begins sampling from the desired disk. This pop-up window can appear in any screen on the analyzer, depending on where you are in the software when you press . For further details on the multiple sample disk mode, refer to Section 3.1, ORDERS screen; Section 6.1, STATUS Screen or Section 7.18, S. DISK MODE SETUP Screen.

### Disk Number 'Confirmation' Pop-up Window

An example of the Disk Number 'Confirmation' pop-up window is shown below.

Stand-by				Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Util
TSH 150 6	C T4 180	<div>Confirmation</div> <div>Current disk no. = 0</div> <div>Resume this operation?</div> <div> <div>Resume</div> <div>Cancel</div> </div>		2	R HCGSTAT 100 3
CEA 0 12	AFP 70			14	FERR 94 15
B12 25 7	P-B12 25			T 10	DIG 88 11
		Dil Uni 18 16	Cups 100	Tips 360	
Set 1 Set 2 100% 75%	Distilled Water	Liquid Waste	Solid Waste 507	Reagent Scan	

### Data Fields

The following is a description of the fields on the Disk Number 'Confirmation' pop-up window. These fields have no user access; they are for display only.

#### Current disk no.

The number of the sample disk currently loaded on the analyzer.



*The sample disks are not physically numbered or coded. The disk number in use must be tracked by the operator.*

## 2.7 Disk Number 'Confirmation' Pop-up Window

---

### **Resume this operation?**

You can either resume operation with the current sample disk or you can cancel to enable you to verify the sample disk number.

### **Window Buttons**

The following is a description of the buttons on the Disk Number 'Confirmation' pop-up window.

A blue rectangular button with the word "Resume" in white text.

Touch this button if you wish to resume operation with the indicated sample disk. The window closes, returns to the screen you were in when the pop-up window appeared and resumes operating.


A green rectangular button with the word "Cancel" in white text.

Touch this button if you wish to cancel operation. The window closes and returns to the screen you were in when the pop-up window appeared.



## 2.8 'Alarm' Pop-up Window

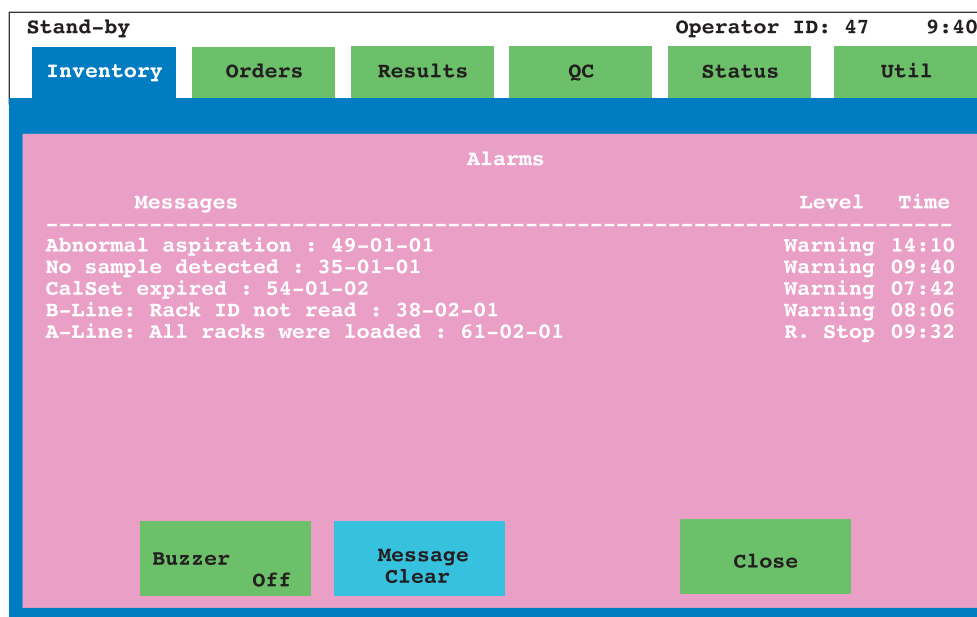
### Introduction

When an alarm condition on the analyzer occurs, the alarm appears on the status line. Additional alarms that may have occurred at the same time must be viewed in the 'Alarm' pop-up window. When you press , a pop-up window appears displaying the last 10 alarm messages. You can delete these messages from the window, but they are still available in Message History. The alarms appear in chronological order on the window. You can print a history of alarm message from the 'Print Message History' pop-up window in the MESSAGE HISTORY screen (UTIL folder).

Multiple occurrences of the same alarm are NOT listed in this window. Therefore, you may wish to clear the alarms each time you access this window. All occurrences of alarms can be found in Message History.

### 'Alarm' Pop-up Window

An example of the 'Alarm' pop-up window is shown below.



Stand-by		Operator ID: 47 9:40			
Inventory	Orders	Results	QC	Status	Util
<b>Alarms</b>					
<b>Messages</b>				<b>Level</b>	<b>Time</b>
Abnormal aspiration : 49-01-01				Warning	14:10
No sample detected : 35-01-01				Warning	09:40
CalSet expired : 54-01-02				Warning	07:42
B-Line: Rack ID not read : 38-02-01				Warning	08:06
A-Line: All racks were loaded : 61-02-01				R. Stop	09:32
Buzzer Off		Message Clear		Close	

### Data Fields

The following is a description of the fields on the 'Alarm' pop-up window. These fields have no user access; they are for display only.

#### Messages

The alarm message and number are listed here. For detailed information on the alarm refer to Chapter 3, Instrument Alarms – *User's Guide*.

## 2.8 'Alarm' Pop-up Window

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### Level

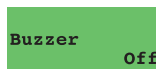
The level of the alarm is displayed here. For detailed information on the alarm levels, refer to Chapter 3, Instrument Alarms – *User's Guide*.

### Time

The time the alarm occurred is displayed here.

### Window Buttons

The following is a description of the buttons on the 'Alarm' pop-up window.



Touch this button to switch the audible alarm off or on. The button toggles from "Off" to "On."



Touch this button to clear the messages on the 'Alarm' pop-up window.

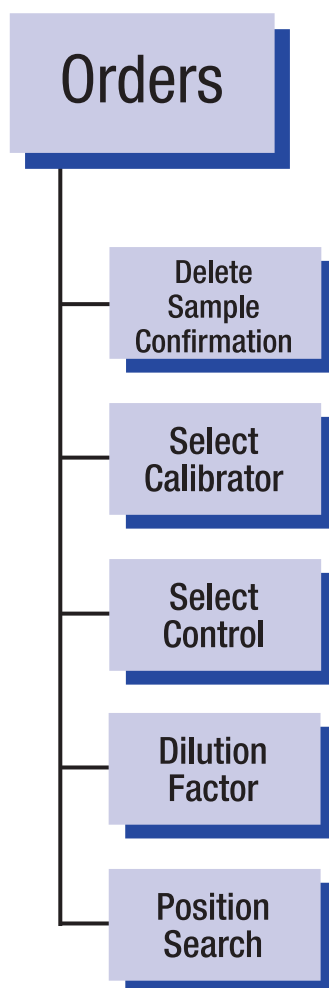
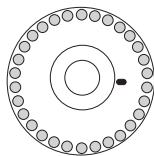


Touch this button to close the 'Alarm' pop-up window and return to the screen where you originally pressed the  key.

---

## Chapter 3

# Orders Screen



## 3.1 ORDERS Screen

### Introduction

On the ORDERS screen, you can manually order samples, check, alter or enter sample information on ordered samples, including ID, sample disk number, rack number, position on the sample disk or rack, and test selection information. You can also search by sample ID or sequence number, print a work list, delete individual sample IDs for data management or denote a sample as pre-diluted.

The ORDERS screen works the same in the STAT mode as in routine operation. The only difference is in the status line (the word "STAT" appears in red near the operator ID) and the Sample ID field changes to read STAT Sample ID.

### ORDERS Screen

An example of the ORDERS screen for the disk system is shown below.

Stand-by		Operator ID: 47			07:40
Inventory	Orders	Results	QC	Status	Util
Sample ID	:	<input type="text"/>	Pre-dil. Off	Sample	
Sequence No.	:	200	Select Control	Dilution Factor	Control Calibrator
Pos.	:	1 - <input type="text"/>	Position Search	Sample Cup Normal	Register
Sample volume	:	ul			
HCG	T3	TSH	CEA	AFP	
HBSAG	T4				

## 3.1 ORDERS Screen

An example of the ORDERS screen for the rack system is shown below.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Util
Sample ID :	<input type="text"/>	Pre-dil. Off	Sample Control Calibrator		
Sequence No. :	200	Select Control	Dilution Factor		
Rack ID - Pos. :	<input type="text"/> - <input type="text"/>	Position Search	Sample Cup Normal	Register	
Sample volume :	ul				
HCG	T3	TSH	CEA	AFP	
HBSAG	T4				

### Data Entry Fields

The following is a description of the entry fields on the ORDERS screen. Touch the field to highlight and activate it.

#### Sample ID


A sample identification occupies this field. It can be up to 22 alphanumeric characters. You can only enter numeric characters from the keyboard, but the host can download alphanumeric characters. If no sample ID is entered, the "@" character is attached to the beginning of the sequence number and becomes the sample ID. Press  to confirm entries. Touch the field again to clear data not confirmed. Individual samples can be deleted by pressing  while in this field.



The Sample ID field changes to read Control ID, Calibrator ID, STAT Sample ID or STAT Control ID depending on the type of sample identification information to be entered.

Control ID appears in this field if the  button is toggled to the "Control" choice. Roche control orders are requested automatically by the software when the control bar code label is read on the sample disk or rack. Test selections are made via the CONTROL DEFINITION screen (UTIL folder).

## 3.1 ORDERS Screen



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

The Calibrator ID field appears if the  button is toggled to the "Calibrator" choice. Calibrators are ordered automatically by the software when the calibrator bar code label is read on the sample disk or rack.

You can search for a sample ID by touching the Sample ID field and typing the desired ID number. Press  to confirm. When you press  while in the Sample ID field, the cursor advances to the Pos. field.

### Sequence no.


The sequence number is displayed here. The available sequence is from 1 to 9999. If the sequence number is 9999, the next number is 1. The roll over to sequence number 1 only occurs when all previous 9999 sequence numbers have been used.


You can assign any sequence number to the sample, provided the number is unused. Touch the field to activate it for data entry. You can search for sequence numbers in this field by either typing the desired sequence number in the field or by using  or .

When the sequence number is at 9999, pressing  does not advance to sequence number 1. Likewise, when the sequence number is 1, pressing  does not return to sequence number 9999.



### Pos.



The position number is comprised of two fields. The first field is the sample disk number. There are 10 disk numbers (0 - 9) that can be used. The second field is the sample disk position. There are 30 available positions on each sample disk. Touch each field to activate it for data entry. Press  to confirm entries.

The sample disk position increments after pressing . When the position number increases to 30 the next position number rolls to 1.



### Rack ID - Pos.

This field is comprised of two fields. The first field is the rack ID number. Leading zeros are added by the system to a manual rack ID entry (e.g., rack "5" becomes "00005"). The number of leading zeroes added depends upon whether the rack ID is setup for four or five digits. The rack ID setup is done by Service at installation.

The second field is the rack position number. Positions 1 to 5 can be used. Press  to confirm entries. The rack position increments after pressing . When the position number increases to 5 the position number returns to 1 and the rack ID clears.

You can search by rack ID and position. Enter the rack ID and position. Press  to confirm entries. Then press  or  to find the desired sample.

## 3.1 ORDERS Screen

### Sample volume

The amount of sample required (in  $\mu\text{l}$ ) based on the tests requested and DOES NOT include dead volume of the container. The sample volume also prints on the work list.

### Screen Buttons

The following is a description of the buttons on the ORDERS screen.

**Pre-dil. Off**

This button can be used to flag a manually-diluted sample with a "P" on the RESULTS screen and on the printout. The result is NOT corrected for any dilution factor. Touch the button to toggle from "Off" to "On."

**Sample  
Control  
Calibrator**

This selection button works like a toggle switch. Touch it once to change the Sample ID field to Control ID. Touch it again to change to Calibrator ID which allows access to the 'Select Calibrator' pop-up window. The default is "Sample." There is a light blue highlight bar that identifies which option is selected. Refer to the button on the right.

**Sample  
Control  
Calibrator**

**Select  
Control**

Use this button to access the 'Select Control' pop-up window and select a pre-defined non-Roche control, or a Roche control with no bar code or a damaged bar code.

**Dilution  
Factor**

Touch a test button and then touch this button to open the 'Dilution Factor' pop-up window. Select the dilution factor if the sample requires dilution. If a dilution factor is selected in the window, the sample is automatically diluted by the analyzer prior to analysis. The available dilution factors are set by the software.

If the text on the button is white, the 'Dilution Factor' pop-up window is not available. This button is only available for assays that are encoded in the diluent bar code as being able to be diluted. For example, you cannot dilute FT3, therefore, you are unable to select automatic dilution on a FT3 sample. The button is also not available if diluent is not on the analyzer.

The assay measuring range is recalculated based on the dilution factor. The resulting diluted sample result is not flagged as outside the measuring range.

## 3.1 ORDERS Screen

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### Position Search

This button accesses the 'Position Search' pop-up window and allows you to search for a sample by disk number and position, provided that sample is not completed.

### Sample Cup Normal Sample Cup Reduced

This button functions like a toggle switch. It allows you to select a reduced dead volume for a sample when using sample cups directly on the sample disk or rack, or on top of a primary sample tube. The button default is "Normal." The default for this feature is set in the KEEP FUNCTION SETUP screen. Touch the button once to select "Reduced." Refer to Chapter 2, System Description – *Reference Guide*, for a table of reduced dead volumes.

### Register

Touch this button to register and confirm your sample orders. If an order was previously registered, the button changes from yellow to green.



*If you change anything on a registered sample order, you must confirm the change by touching*

Register

*again, even if the button is green.*

### T4

There are 15 test buttons available for test selection. Touch each button to make a test selection for the sample. Touch it again to deselect. When the test is selected, the button color changes from green to light blue. All assays loaded on the reagent disk appear on the screen. They are sorted by test number order.

## Keyboard Functions

The following is a description of the keys that are active in the ORDERS screen.



If the cursor is in the Sequence No. field, the software advances through assigned sequence numbers. Any gaps in the sequence are skipped and there is no roll over (i.e., when the last programmed sequence number is reached, no further numbers are listed).



If the cursor is in the Sequence No. field, the software goes back through assigned sequence numbers. Any gaps in the sequence are skipped and there is no roll over (i.e., when the first programmed sequence number is reached, no further numbers are listed).








## 3.1 ORDERS Screen

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Confirms an entry in the Sample ID, Sequence No. or either Pos. field.



If the cursor is in the Sample ID or Sequence no. field, the Delete Sample 'Confirmation' pop-up window appears. From here you can delete a sample record from the system. This key only works on sample IDs or sequence numbers that have been entered into the system by touching  or that were downloaded from the host. If you entered incorrect information into a field and have not pressed , pressing  functions like a backspace key to delete the information. If you already pressed , but not , then you must touch the field to overwrite the entry.




The last action cleared with  is undone if this key is pressed immediately.



All unprocessed samples on the current sample disk or all programmed/downloaded samples in the rack system are printed on a work list. All required inventory information is included (on the disk system only). Pressing the key a second time stops the analyzer from sending more data to the printer. Printing may not stop immediately.

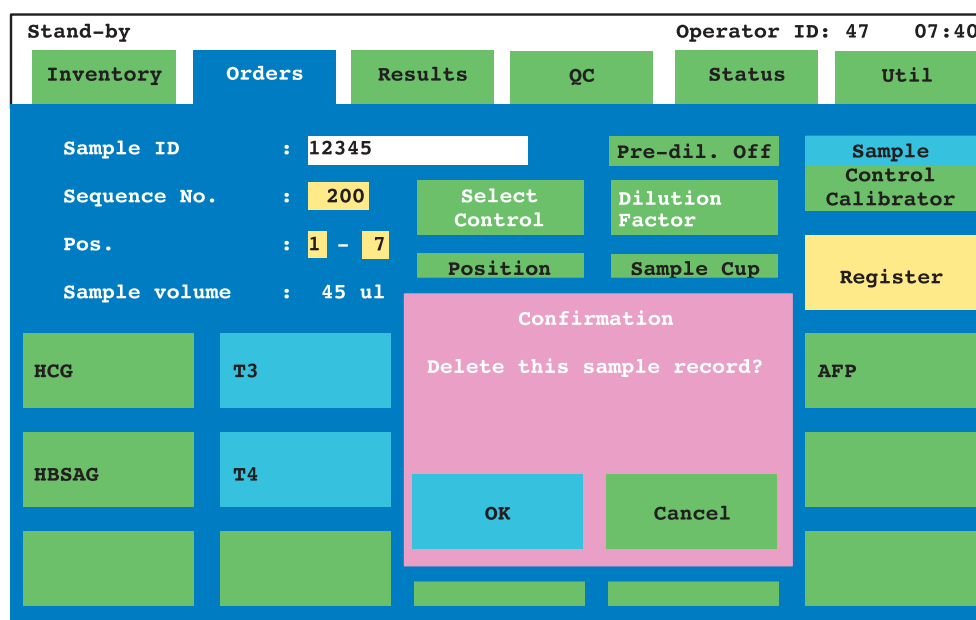
## 3.2 Delete Sample 'Confirmation' Pop-up Window

### Introduction

You can delete registered samples from the ORDERS screen. If you press  while in either the Sample ID or Sequence No. fields, the Delete Sample 'Confirmation' pop-up window appears.

### Delete Sample 'Confirmation' Pop-up Window

An example of the Delete Sample 'Confirmation' pop-up window that appears in the ORDERS screen is shown below. The window appears the same in both disk and rack systems.



### Window Buttons

The following is a description of the buttons on the Delete Sample 'Confirmation' pop-up window.

OK


Touch this button to delete the selected ID's data. The window closes and returns to the ORDERS screen, the Sample ID field clears and the sequence number increases by one.

Cancel

Touch this button if you do NOT want to delete the selected ID's data. The window closes and returns to the ORDERS screen.

### 3.3 'Select Calibrator' Pop-up Window

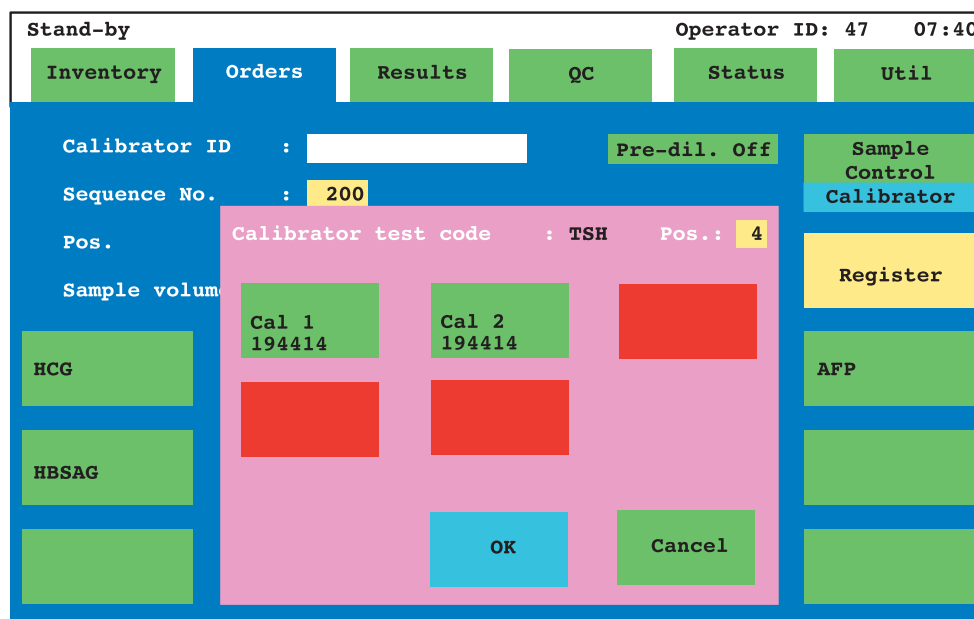
#### Introduction

You can manually select calibrators in the 'Select Calibrator' pop-up window. Access this window by toggling the  button to the "Calibrator" choice. Then touch the assay button for which you want to manually select calibrators. This is a useful window if you pour your calibrators into a container other than the CalSet vial.

For the calibrator levels to appear in the window, the assay must have been previously calibrated using bar-coded CalSet vials. For further details, refer to Section 3.4, How To Manually Select a Calibrator – Disk System, or Section 3.5, How To Manually Select a Calibrator – Rack System – *Tutorial Guide*.

#### 'Select Calibrator' Pop-up Window

An example of the 'Select Calibrator' pop-up window that appears in the ORDERS screen is shown below. The window appears the same in both disk and rack systems.



The screenshot shows the 'Select Calibrator' pop-up window. At the top, there is a status bar with 'Stand-by' on the left and 'Operator ID: 47 07:40' on the right. Below this is a navigation bar with buttons: 'Inventory', 'Orders' (highlighted), 'Results', 'QC', 'Status', and 'Util'. The main area of the window is blue. On the left, there are labels for 'Calibrator ID', 'Sequence No.', 'Pos.', and 'Sample volume'. The 'Calibrator ID' field is empty, 'Sequence No.' is '200', 'Pos.' is '4', and 'Sample volume' is 'HCG'. On the right, there is a 'Pre-dil. Off' button and a 'Sample Control Calibrator' button. Below these is a 'Register' button. In the center, there is a pink box containing a table of calibrators. The table has two columns: 'Cal 1' and 'Cal 2'. Both columns show the value '194414'. Below the table are 'OK' and 'Cancel' buttons. On the far right, there are buttons for 'AFP' and another empty button.

Cal 1	Cal 2
194414	194414

### 3.3 'Select Calibrator' Pop-up Window

---

#### Data Entry Fields

The following is a description of the entry fields on the ORDERS screen. Touch the field to highlight and activate it.

##### Calibrator test code

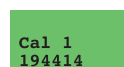
The test code of the assay button touched. There is no access to this field.

##### Pos.

The position number of the reagent disk of the assay button touched. If you change the position number, press  to confirm the entry.

#### Window Buttons

The following is a description of the buttons on the 'Select Calibrator' pop-up window.



The calibrator level and lot number appear on the button. Touch the appropriate calibrator button to select it. The button changes from green to light blue when selected.



Touch this button to accept the selected calibrator level. The window closes and returns to the ORDERS screen.



Touch this button if you do not want to accept the selected calibrator level. The window closes and returns to the ORDERS screen.

#### Keyboard Functions

The following is a description of the keys that are active in the 'Select Calibrator' pop-up window.



Confirms an entry in the Pos. field.

## 3.4 'Select Control' Pop-up Window

### Introduction

The 'Select Control' pop-up window from the ORDERS screen allows you to select a pre-defined non-Roche control, or a Roche control with no bar code or a damaged bar code. For further details on manual control selection, refer to Section 2.5, Initiate Calibration/Control Measurement – Disk System or Section 2.6, Initiate Calibration/Control Measurement – Rack System – *Tutorial Guide*.

### 'Select Control' Pop-up Window

An example of the 'Select Control' pop-up window that appears in the ORDERS screen is shown below. The window appears the same in both disk and rack systems.

Stand-by Operator ID: 47 07:40

Inventory Orders Results QC Status Util

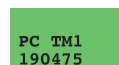
Sample ID : Pre-dil. Off Sample

PC TM1 190475	PC TM2 190476	PC CARD1 193301	PC CARD2 193302	PC U1 192063
PC U2 192094	PC TSH 194383			

OK Cancel

### Window Buttons

The following is a description of the buttons on the 'Select Control' pop-up window.



Touch the appropriate control button to select it. The button changes from green to light blue when selected.

### 3.4 'Select Control' Pop-up Window

---

A blue rectangular button with the text "OK" in white, centered.

Touch this button to accept the selected control level. The window closes and returns to the ORDERS screen.

A green rectangular button with the text "Cancel" in white, centered.

Touch this button if you do not want to accept the selected calibrator level. The window closes and returns to the ORDERS screen.

## 3.5 'Dilution Factor' Pop-up Window

### Introduction

The 'Dilution Factor' pop-up window from the ORDERS screen allows you to select a dilution factor. When a dilution factor is selected, the test button displays the selected factor. Certain assays should not be diluted. Refer to the *Dilution* section of the package insert for recommended dilutions.

HCG  
Dil.= 100

This window is only available for assays that are encoded in the diluent bar code as being able to dilute and when diluent is on the analyzer.

### 'Dilution Factor' Pop-up Window

An example of the 'Dilution Factor' pop-up window is shown below. The window appears the same in both disk and rack systems.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Util
Sample ID	:	<input type="text"/>	Pre-dil. Off	Sample Control	
Sequence No.	:	200	Select	Dilution	Calibrator
Pos.					Register
Sample vol					
HCG					AFP
HBSAG					
		Dilution Factor		HCG	
		2	5	No Dil.	
		10	20		
		50	100	Close	

### Window Buttons

The following is a description of the buttons on the 'Dilution Factor' pop-up window.

2

There are six available dilution selection buttons and a button to select no dilution. When selected, the dilution button changes color from green to light blue.

### 3.5 'Dilution Factor' Pop-up Window

---

Depending upon which dilution factor is selected, different volumes of sample and diluent are aspirated to complete the dilution. Some dilutions are completed in two steps. Refer to the table below.

	First Dilution		Second Dilution	
Dilution Ratio	Sample	Diluent	Diluted Sample	Diluent
1:2	50 µL	50 µL	–	–
1:5	40 µL	160 µL	–	–
1:10	20 µL	180 µL	–	–
1:20	20 µL	180 µL	100 µL	100 µL
1:50	20 µL	180 µL	40 µL	160 µL
1:100	20 µL	180 µL	20 µL	180 µL

For information on the steps performed during a sample dilution, refer to Section 3.2, Detailed Assay Sequence – *Reference Guide*.

Close

Touch this button to close the window when you have selected the appropriate dilution factor. Closing the window without selecting a dilution factor or selecting “no dilution” results in the sample being performed without a dilution.



## 3.6 'Position Search' Pop-up Window

### Introduction

The 'Position Search' pop-up window from the ORDERS screen allows you to search for a sample by disk number and position, or by rack ID and position, provided the sample is not yet completed.

### 'Position Search' Pop-up Window

An example of the 'Position Search' pop-up window for the disk system is shown below.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Util
Sample ID : <input type="text"/>		Pre-dil. Off		Sample Control Calibrator	
Sequence No. : 200		Select	Dilution		
Pos. : 1 - <input type="text"/>				Register	
Sample volume : ul					
HCG	T3	<div>Position Search</div> <div>Disk no. : <input type="text"/></div> <div>Position no. : <input type="text"/></div> <div>Search Close</div>		AFP	
HBSAG	T4				

## 3.6 'Position Search' Pop-up Window

An example of the 'Position Search' pop-up window for the rack system is shown below.


The screenshot shows a software interface with a top navigation bar containing 'Stand-by', 'Operator ID: 47', and '07:40'. Below this is a menu bar with 'Inventory', 'Orders', 'Results', 'QC', 'Status', and 'Util'. The main area has a blue background with several fields and buttons. On the left, there are labels for 'Sample ID', 'Sequence No.', 'Rack ID - Pos.', and 'Sample volume'. In the center, a pink 'Position Search' pop-up window is displayed, containing 'Rack ID' and 'Position no.' fields, and 'Search' and 'Close' buttons. To the right of the pop-up, there are buttons for 'Pre-dil. Off', 'Dilution', 'Sample Control Calibrator', and 'Register'. At the bottom, there are buttons for 'HCG', 'T3', 'HBSAG', 'T4', and 'AFP'.

### Data Entry Fields

The following is a description of the entry fields on the 'Position Search' pop-up window. Touch the field to highlight and activate it.




#### Disk no.


The sample disk number. When you enter the window, the cursor is flashing in this field. There are 10 disk numbers (0 - 9) that can be used. Press  to confirm entries.



#### Rack ID

The rack ID number. Leading zeros are added by the system to a manual rack ID entry (e.g., rack "5" becomes "00005"). Press  to confirm entries. The number of leading zeroes added depends upon whether the rack ID is setup for four or five digits. The rack ID setup is done by Service at installation.

#### Position no.

The position number on the sample carrier. It can be 1-30 on a disk system and 1-5 on a rack system. Press  to confirm entries.

## 3.6 'Position Search' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the 'Position Search' pop-up window.



Touch this button to initiate the search for the desired sample. The window closes and returns to the ORDERS screen. The desired sample is displayed on the screen.



Touch this button to close the window to cancel the search and return to the ORDERS screen.

### Keyboard Functions

The following is a description of the keys that are active in the 'Position Search' pop-up window.



Confirms an entry in the Disk no., Rack ID or Position no. field.

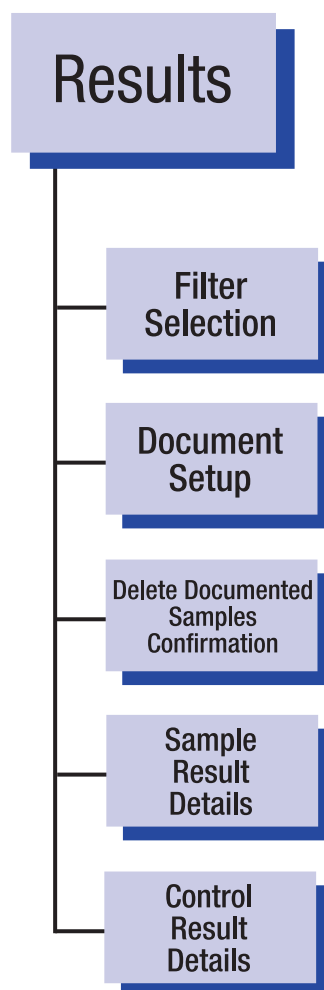
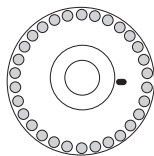
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## Notes

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## Chapter 4

# Results Screen



## 4.1 RESULTS Screen

### Introduction

The RESULTS screen displays sample information consisting of the following:

- sample ID number
- sample sequence number
- sample position (disk or rack)
- sample type; sample, control or STAT samples (by a change in the Sample ID field)
- number of samples in the filter
- test buttons displaying results for the sample.

You can search for results in this screen by sample ID or sequence number and upload results to the host multiple times.

All samples can be viewed, printed or uploaded from this screen. It holds up to 600 results, depending upon the number of orders in the system. Results are then overwritten on a first in, first out (FIFO) basis. Details of each result can be checked by touching the specific test button. You can delete documented samples from the database thereby freeing additional space.

### RESULTS Screen

An example of the RESULTS screen for the disk system is shown below.

S. Stop		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Util
Sample ID : 23456 P		Filter Off		Document	
Sequence No. : 1					
Pos. : 1 - 7		Samples : 101		Delete Doc. Samples	
HCG 14:46 189					

## 4.1 RESULTS Screen




An example of the RESULTS screen for the rack system is shown below.

S. Stop		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Util
Sample ID : 23456 P		Filter Off		Document	
Sequence No. : 1 Documented					
Rack ID - Pos. : 0005 - 3		Samples : 101		Delete Doc. Samples	
HCG 14:46 189					

### Data Entry Fields

The following is a description of the data entry fields on the RESULTS screen. Touch the field to highlight and activate it.




#### Sample ID

Type the sample ID number in this field. Confirm the entry by pressing . You can search for samples or controls in this field by pressing  or .

#### P

Samples that were designated as pre-diluted (i.e., manually diluted) in the ORDERS screen are noted on the RESULTS screen with a "P" that appears at the end of the Sample ID field.

#### Sequence No.

The sample sequence number. You can search for a specific sequence number in this field by typing the sequence number and pressing , or by touching the field and pressing  or .

#### Documented

This word appears next to the sequence number after the sample is documented.



#### Pos.

The position number occupied by the selected sample or sequence number. This field is for display only. You cannot search by position number.

## 4.1 RESULTS Screen

### Rack ID - Pos.

The rack ID and position number occupied by the selected sample or sequence number. This field is for display only. You cannot search by rack ID or position number.

### Samples

The number of samples in the filter as determined by the settings in the 'Filter Selection' pop-up window.

### Screen Buttons

The following is a description of the buttons on the RESULTS screen.



Filter  
Off

Touch this button to access the 'Filter Selection' pop-up window. This button also tells you whether the filter function is active. "Filter Off" means filtering is not active. "Filter On" means filtering is active.



Document

Touch this button to access the 'Document Setup' pop-up window.



Delete  
Doc. Samples

Touch this button to access the Delete Documented Samples 'Confirmation' pop-up window.

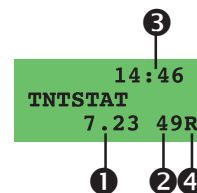


14:46  
TNTSTAT  
7.23 49

Touching the specific button accesses the 'Result Details' pop-up window.

Up to 15 test buttons are displayed for each sample. Data appears on the buttons in real time; new data appears every 42 seconds. The data displayed on the test button can include the following:

- 1 test result.
- 2 any possible data alarm. If there is more than one data alarm for a result, then only the alarm with the highest priority appears. For further details on data alarm priorities, refer to Chapter 2, Data Alarms – *User's Guide*.
- 3 the time the result is available.
- 4 an S, B or R indicating that the sample was blocked by the system, blocked by the operator or released by the operator, respectively.





## 4.1 RESULTS Screen

---

### Keyboard Functions

The following is a description of the keys that are active while in the RESULTS screen.



If the cursor is in the Sample ID or Sequence No. field, you can search the next sequence number and update the screen. Gaps in the sequence are skipped and there is no roll over (i.e., when the last sequence number is reached, no further numbers are listed).



If the cursor is in the Sample ID or Sequence No. field, you can search the previous sequence number and update the screen. Gaps in the sequence are skipped and there is no roll over (i.e., when the first sequence number is reached, no further numbers are listed).



Confirms an entry in the Sample ID or Sequence No. field.




Prints, uploads or prints and uploads a report for sample ID displayed. The action depends upon the document option chosen in the DOCUMENTATION SETUP screen (UTIL folder).

Pressing the key a second time stops the analyzer from sending more data to the printer. Printing may not stop immediately. Also, pressing the key a second time does not stop the upload to the host.

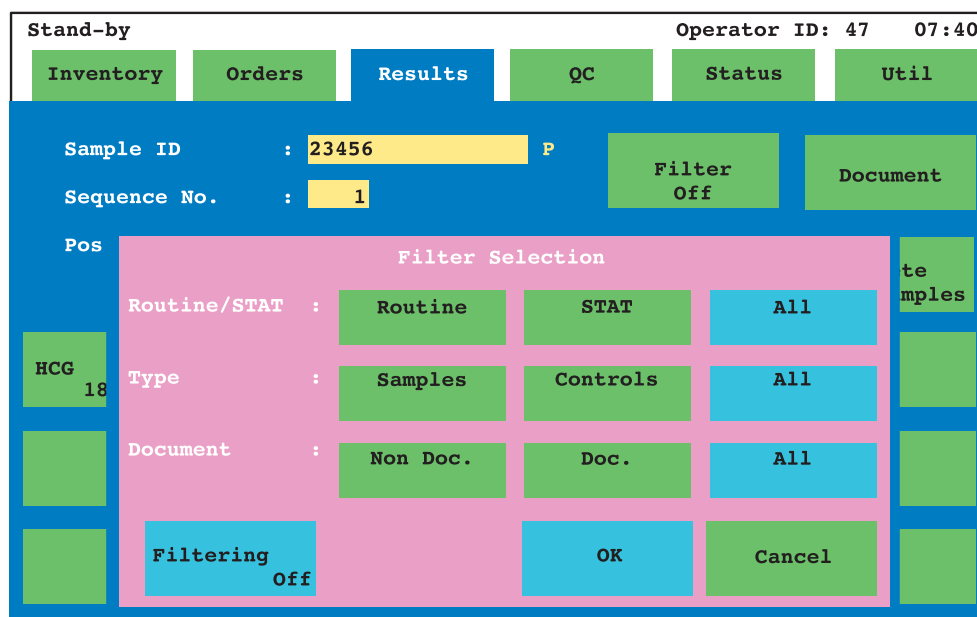
## 4.2 'Filter Selection' Pop-up Window

### Introduction

When you touch , the 'Filter Selection' pop-up window appears. In this window, you can choose to filter the type of samples you want to view, document or print. You can filter by Samples, Type or Document. The combination chosen in this window affects the number displayed in the `Samples` field on the RESULTS screen.

### 'Filter Selection' Pop-up Window

An example of the 'Filter Selection' pop-up window is shown below for the disk system. The window appears the same in both disk and rack systems.



### Data Entry Fields

The following is a description of the data entry fields on the 'Filter Selection' pop-up window. Touch the button to highlight your selection.

#### Routine/STAT

This field filters the samples; "Routine," "STAT" or "All." Touch the button to select your choice. When selected, the button changes from green to light blue. The default choice is "All."

#### Type

This field filters the sample type; "Samples," "Controls" or "All." Touch the button to select your choice. When selected, the button changes from green to light blue. The default choice is "All."

## 4.2 'Filter Selection' Pop-up Window

---

### Document

This field filters the documentation selection; 'Non Doc.', "Doc." or "All." Touch the button to select your choice. When selected, the button changes from green to light blue. The default choice is "All."

### Window Buttons

The following is a description of the buttons on the 'Filter Selection' pop-up window.



Touch this button to toggle to activate or deactivate filtering.



Touch this button to accept the filtering selections and return to the RESULTS screen.



Touch this button if you do not want to accept the filtering selections. The window closes and returns to the RESULTS screen.

## 4.3 'Document Setup' Pop-up Window

### Introduction

When you touch **Document**, the 'Document Setup' pop-up window appears. In this window, you can select a sequence number range of samples to document. A result is documented by either printing, uploading or printing AND uploading. Results can be printed or uploaded multiple times. The means of documentation initiated depends upon the document option chosen in the DOCUMENTATION SETUP screen (UTIL folder).

### 'Document Setup' Pop-up Window

An example of the 'Document Setup' pop-up window is shown below for the disk system. The window appears the same in both disk and rack systems.

Stand-by Operator ID: 47 07:40

Inventory Orders Results QC Status Util

Sample ID : 23456 P

Sequence No. : 1 Documented

Pos. : 1 - 7

Samples : 101

Document Setup

First seq. no. : 1

Last seq. no. : 9999

OK Cancel

Filter Off Document

Delete Doc. Samples

HCG 14:46 189

### Data Entry Fields

The following is a description of the data entry fields on the 'Document Setup' pop-up window. Touch the field to highlight and activate it.

#### First seq. no.

Type the first sequence number (1-9999) of the range of samples to document.

Press  to confirm entries.

#### Last seq no.

Type the last sequence number (1-9999) of the range of samples to document.

Press  to confirm entries.

## 4.3 'Document Setup' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the 'Document Setup' pop-up window.



Touch this button to initiate documentation of the selected range of samples. The window closes and returns to the RESULTS screen.



Touch this button if you do not want to accept the range of samples to document. The window closes and returns to the RESULTS screen.

### Keyboard Functions


The following is a description of the keys that are active while in the 'Document Setup' pop-up window.



Confirms an entry in the First seq. no. or Last seq. no. field.

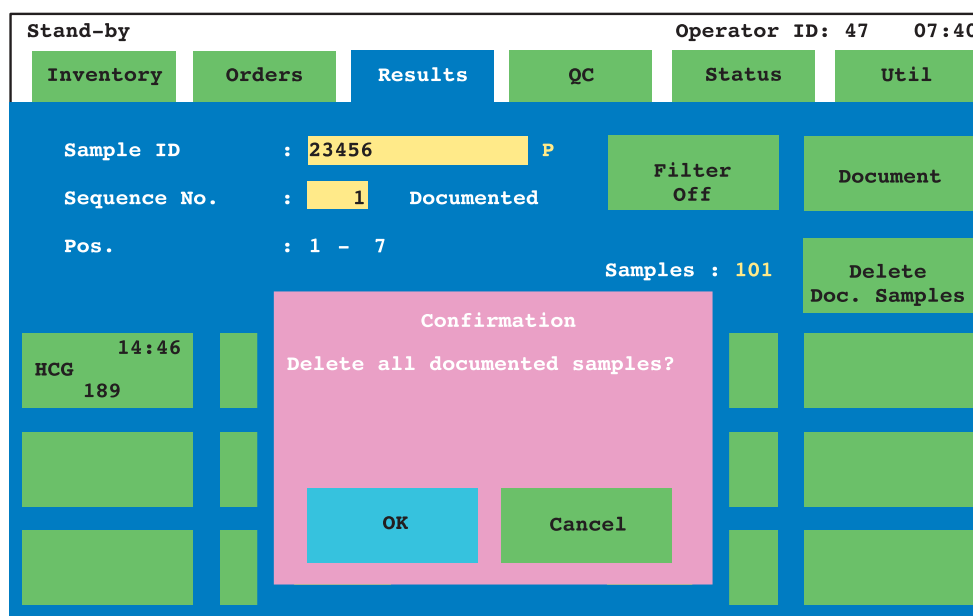
## 4.4 Delete Documented Samples 'Confirmation' Pop-up Window

### Introduction

When you touch , the Delete Documented Samples 'Confirmation' pop-up window appears. Deleting all documented samples in the system increases the space in the database and frees the corresponding sequence numbers.

### Delete Documented Samples 'Confirmation' Pop-up Window

An example of the Delete Documented Samples 'Confirmation' pop-up window is shown below for the disk system. The window appears the same in both disk and rack systems.



### Window Buttons

The following is a description of the buttons on the Delete Documented Samples 'Confirmation' pop-up window.



Touch this button to delete all documented samples. The window closes and returns to the RESULTS screen.



Touch this button if you do not want to delete all documented samples. The window closes and returns to the RESULTS screen.

## 4.5 'Result Details' Pop-up Window

### Introduction

You can check the details of the result of a test by touching the desired test button on the RESULTS screen to access the 'Result Details' pop-up window. In this window you can view test results compared to the expected values of the assay, any flags generated on the test and the status of the test result. You can also determine when the test result was completed. The data fields differ slightly for a sample versus a control.

### 'Result Details' Pop-up Window for a Sample

An example of the 'Result Details' pop-up window for a sample is shown below for the disk system. The window appears the same in both disk and rack systems.

Stand-by		Operator ID: 47		07:40	
Inventory	Orders	Results	QC	Status	Util
Sample ID : 7635446				Document	
Sequence No. : 154		Do			
Pos. : 1 - 7				Delete oc. Samples	
14:16 TNTSTAT 7.23 49		TNTSTAT Sampling time: 14:06 Ready time : 14:16 Result : 7.23 ng/ml Lower limit : 0.00 Upper limit : 0.10 Note : Dil. factor : Flags : 49 Status : Released Signal :			
		Block		Close	

### Data Fields

The following is a description of the fields on the 'Result Details' pop-up window for a sample. These fields have no user access; they are for display only.

#### Test Code

The test abbreviation assigned to the selected test.

#### Sampling time

The time when the test was pipetted from the sample disk or rack.

#### Ready time

The time when the test result was completed.

## 4.5 'Result Details' Pop-up Window

---

### **Result**

The test result and unit. If the software is unable to calculate the result, "No Value" appears in this field.

### **Lower limit**

The lower limit of the expected values for the test. The expected values can be changed in the 'Test Conditions Details' pop-up window (UTIL folder).

### **Upper limit**

The upper limit of the expected values for the test. The expected values can be changed in the 'Test Conditions Details' pop-up window (UTIL folder).

### **Note**

A result message that is displayed if a predefined result condition exists. These messages are set in the software and are not user-definable.

The messages are "reac.", "n-reac." and "border." They are limited to qualitative assays. This note appears on the sample printouts and is not sent to the host.

### **Dil. factor**

The dilution factor selected in the 'Dilution Factor' pop-up window. If no dilution was selected, the field is blank.

### **Flags**

Any flags generated by the system during result measurement. A list of data flags and their descriptions is found in Chapter 2, Data Alarms – *User's Guide*.

### **Status**

The status of the test result. The status may be empty, "Released" or "Blocked." If the field is empty, it means there was no user interaction with the result (i.e., you did not release or block the result).

### **Signal**

The signal generated by the assay result. This field appears only if effective signal is activated. Effective signal is set during installation of the analyzer. Contact Technical Support for assistance.



## 4.5 'Result Details' Pop-up Window

### 'Result Details' Pop-up Window for a Control

An example of the 'Result Details' pop-up window for a control is shown below for the disk system. The window appears the same in both disk and rack systems.

Stand-by		Operator ID: 47		07:40	
Inventory	Orders	Results	QC	Status	Util
Sample ID : PC TM1				Document	
Sequence No. : 15		Do		Delete	
Pos. : 1 - 21				oc. Samples	
CEA 14:30 4.81	PSA 14:30 11.63	CEA Sampling time: 14:11 Ready time : 14:30 Result : 4.81 ng/ml Target lower : 3.50 upper : 5.36 Note : Dil. factor : Flags : Status : Released Signal : Block Close			

### Data Fields

The following is a description of the fields on the 'Result Details' pop-up window for a control. These fields have no user access; they are for display only. The fields are the same as for a sample with the exception of Upper limit and Lower limit fields. Only the corresponding fields are explained here.

#### Target lower

The lower end of the control range. The range is encoded in the control bar code card or entered in the 'Control Definition Details' pop-up window/CONTROL DEFINITION screen/UTIL folder. The control range appears on printouts in the Expected Value field.

#### upper

The upper end of the control range. The range is encoded in the control bar code card or entered in the 'Control Definition Details' pop-up window/CONTROL DEFINITION screen/UTIL folder. The control range appears on printouts in the Expected Value field.


## 4.5 'Result Details' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the 'Result Details' pop-up window.



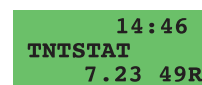
This button toggles between "Block" and "Release." The default is "Block." When you are unsure of a result, touch this button to block the result, then touch . Thereafter, the Status field says "Blocked." The pop-up window closes and the result is blocked. The test button on the RESULTS screen changes from green to yellow, and a "B" is added. Blocked results are printed and uploaded to the host with a "B" status.

A yellow rectangular button with black text. The text is arranged in three lines: '14:46' on the top line, 'TNTSTAT' on the middle line, and '7.23 49B' on the bottom line.

14:46  
TNTSTAT  
7.23 49B

You can only block results if automatic options (printing and/or uploading) are OFF. Automatic options are set in the DOCUMENTATION SETUP screen (UTIL folder).

If you access the pop-up window again and touch this button again, the status changes to "Released." Upon closing the window, the button changes back to green and the "B" is replaced with an "R." You can only release results that are blocked by the user. You cannot release results that are blocked by the system.

A green rectangular button with black text. The text is arranged in three lines: '14:46' on the top line, 'TNTSTAT' on the middle line, and '7.23 49R' on the bottom line.

14:46  
TNTSTAT  
7.23 49R

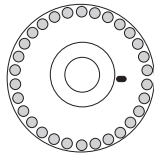


Touch this button when you want to close the window and return to the RESULTS screen.

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## Chapter 5

### QC Screen



QC

## 5.1 QC Screen

### Introduction

The QC screen displays the following information:

- assay test code
- unit of measure
- lot number of reagent
- the last calibration date (L-Cal or R-Cal)
- control lot number.

Four controls can be displayed for an assay. The defined controls are shown in the green button to the right of the Test no. field.

Up to 60 charts (assay/control combination) are calculated and displayed in this screen. Each chart contains up to 60 lines. The oldest data appears at the bottom of the screen. When the 60<sup>th</sup> chart is stored, the 10 oldest charts are marked with a red message, "This data will be deleted." When the 61<sup>st</sup> chart is stored, the oldest chart is automatically deleted (FIFO). You cannot manually choose which chart should be deleted.

You can block control results when the selected result is highlighted. The text turns red, a "B" appears to the right of the result and the statistics are recalculated.

### QC Screen

An example of the QC screen is shown below.

Stand-by				Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Util
<b>HCGSTAT</b>		mIU/ml	Test no. : 17	PC U1	
Reagent lot no. : 193367				PC U2	
Last L-Cal date : 03/16/1998			Control lot : 192093		
n=5 mean= 7.98 SD= 0.227 CV = 2.84					
median= 8.01 min= 7.59 max= 8.16					
-----			5.73	8.13	10.63
03/25/1998 09:49	8.00			x	UP
03/23/1998 09:05	8.12			x	
03/20/1998 08:58	8.01			x	
03/16/1998 11:50	8.16			x	
03/16/1998 10:36	7.59			x	
03/16/1998 08:05	No Value 258	B			Page 1/1
					DOWN

## 5.1 QC Screen

---

### Data Fields

The following is a description of the data fields on the QC screen. These fields have no user access; they are for display only. Only the **Test no.** field is accessible; touch the field to highlight and activate it.


#### **Test code**

The test abbreviation assigned to the selected test.

#### **Unit**

The unit of measure for the selected test. The unit of measure is selected in the TEST CONDITIONS screen (UTIL folder).

#### **Test no.**

The test number of the selected test. Select a test by typing the test number in the field or by pressing . Test numbers are found in the TEST CONDITIONS screen (UTIL folder).

#### **Reagent lot no.**

The lot number of the selected test.

#### **Last L-Cal date**

#### **Last R-Cal date**

The date of the assay's last valid calibration for the lot of reagent.

#### **Control lot**

The lot number of the control highlighted in blue on the green button to the right of the **Test no.** field.

#### **n**

The number of control results for the chart (assay/control combination). You must have at least five results to generate statistics. Blocked values are not included in the statistics.

#### **mean**

The mean value of all control results is indicated.

#### **SD**

This field displays the standard deviation.

#### **CV**

The coefficient of variation is displayed in this field.

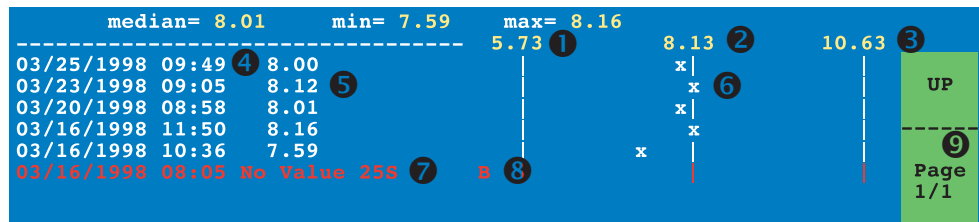
#### **median**

The median of the control results is displayed here.

#### **min/max**

Displays the minimum and maximum control result of all results on the chart.

## 5.1 QC Screen



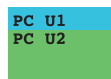
- ❶ The lower limit of the control range.
- ❷ The target value of the control.
- ❸ The upper limit of the control range.
- ❹ The date and time the control result was measured.
- ❺ The control result.
- ❻ The control result displayed graphically as an "x."
- ❼ Any data flags that occurred at the same time of the control result.
- ❽ If a control result is blocked, a "B" appears here.

### ❾ Page 1 of x

A control chart can consist of a maximum of five pages. This field indicates which page you are viewing.

## Screen Buttons

The following is a description of the buttons on the QC screen.



Touch the control level you want to view. When selected it is highlighted with a light blue bar. Up to four controls appear on this button.



Touch a control result to highlight it and then touch this button scroll up through the results on the page.



Touch a control result to highlight it and then touch this button scroll down through the results on the page.

## 5.1 QC Screen

---

### Keyboard Functions

The following is a description of the keys that are active while in the QC screen.



If the cursor is in the `Test no.` field, you can advance to the next sequential test number.

If a control result line is highlighted, you can advance from page to page in a control chart. When the maximum of a chart is reached, pressing



again advances to the next available lot number for the control level.



If the cursor is in the `Test no.` field, you can back up to the previous sequential test number.

If a control result line is highlighted, you can advance from page to page in a control chart. When the maximum of a chart is reached, pressing



again advances to the previous available lot number for the control level.



Blocks a result when a selected control result is highlighted. Pressing this key again releases the result and returns the text to its previous state and recalculates the statistics.



Prints a QC report for the control level displayed.

Pressing the key a second time stops the analyzer from sending more data to the printer. Printing may not stop immediately. Also, pressing the key a second time does not stop the upload to the host.

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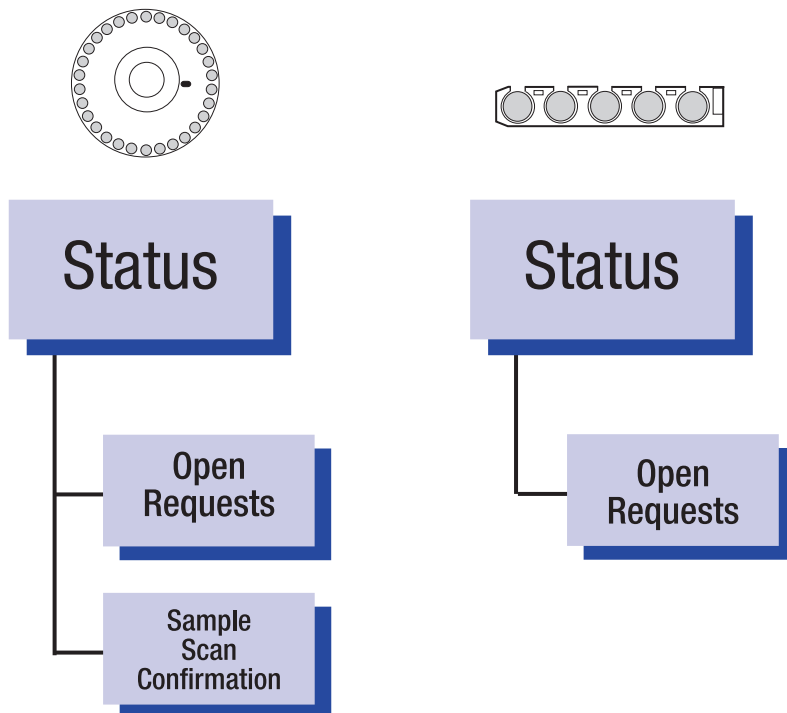
## Notes



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## Chapter 6

# Status Screen



# 6.1 STATUS Screen

## Introduction

The STATUS screen is used to monitor the progress through sample processing. It displays the sample status, and allows entry of operator ID and deletion of open requests. On the disk system, a sample scan is requested from this screen.

## STATUS Screen

An example of the STATUS screen for the disk system is shown below.

Operation

Operator ID: 4713:00

InventoryOrdersResultsQCStatusUtil

Sample Disk Status

1 Remov	2 Remov	3 Remov	4 Remov	5 Compl
6 Compl	7 Compl	8 Compl	9 Compl	10 Compl
11 Compl	12 Incmp	13 Compl	14 Compl	15 Compl
16 Compl	17 Compl	18 Proc	19 Proc	20 Proc
21 Proc	22 Proc	23 Proc	24 Proc	25 Smpl
26 Occup	27 Occup	28 Stop	29 Empty	30 Empty

Operator ID : 47

Disk No. : 1

Last result at : 13:46

Sample Scan

Open Reqs.



## 6.1 STATUS Screen

---

### Tray Part 1 (Screen 2)

Screen 2 holds up to five racks. Row 1 is always empty; it is only utilized in screen 1. The screen updates from top to bottom (i.e., the rack that was processed first appears in row 2 and continues down to row 6. When the next rack is processed, this rack moves from screen 2, row 6 to screen 3, row 2). Therefore, as more racks are processed, they move into tray part 2.

When you access the STATUS screen from another folder, this is the screen that appears first.

### Tray Part 2 (Screen 3)

Screen 3 holds up to five racks. Row 1 is always empty; it is only utilized in screen 1. Like screen 2, screen 3 updates from top to bottom. When all five rows are full, screen 3, row 6 moves to screen 4, row 2. Therefore, as more racks are processed, they move into tray part 3.

### Tray Part 3 (Screen 4)


Screen 4 holds up to five racks. Row 1 is always empty; it is only utilized in screen 1. Like screens 2 and 3, screen 4 updates from top to bottom. When all five rows are full, screen 4, row 6 displays the first rack processed. When the entire output tray of the C-Line is full, the racks then fill the output buffer. The analyzer displays alarm 63-02-02 (C-Line tray is full). When the C-Line and output buffer are completely filled, the analyzer displays alarm 62-02-04 (C-Line and buffer full).



#### Rack ID

The rack ID for the displayed rack. The ID appears as a five-digit number regardless of how many digits were entered for the ID in the ORDERS screen. This field is for display only; there is no user access.

#### Operator ID


Type a two-digit operator identification number. Press  to confirm the entry. This number is laboratory specific. Any number from 01 to 99 can be entered; "00" is not possible. The default operator ID is "01."

#### Last result at:

This field gives you an approximate time when the last sample result will be completed based on the samples currently known to the system or in process.



#### Disk No.

This is the sample disk currently displayed on the screen. To see the status of any other sample disk, touch the field, type a number (0 - 9) and press .

## 6.1 STATUS Screen







### Screen Buttons

The following is a description of the buttons on the STATUS screen.



Touch this button to access the 'Sample Position Status' pop-up window.

Sample status buttons indicate the status of each sample on the sample disk or rack. The upper right number on the button represents the sample's position number on the disk (up to 30) or the rack (up to 5). Eight kinds of sample status are available. Not all status conditions are available on each system. Differences are noted in the table below by a disk or a rack graphic.

System	Display	Report Text	Button Color	Text Color	Sample Status
Both	Empty	Empty	Green	Black	An empty disk or rack position, ready for a sample.
	Occup	Occupied	Lt. Blue	Black	The sample position is assigned or empty (i.e., during a sample scan, the bar code reader cannot distinguish between a cup on the disk or an empty position).
	Occup	Occupied	Lt. Blue	Black	The rack position is occupied, but not sampled.
Both	Smpl	Active Sample	Purple	Black	The sample currently being pipetted. On the rack system, this status only appears in row 1, screen 1 (Output Buffer).
Both	Proc	In process	White	Purple	The sample is in process (i.e., all assays have been pipetted), but results are not ready.
Both	Incmp	Incomplete	Yellow	Red	There was an error during processing, or the sample has a result greater than the measuring range. (Not for calibrators.)
	Compl	Complete	White	Black	The sample is complete and can be removed from the disk. (Not for calibrators.)
	Compl	Complete	White	Black	The sample is complete and can be removed from the rack on the C-Line.
	Remov	Removable	White	Black	The calibrator can be removed from the disk. (Not for samples or controls.)
	Stop	Stop	Red	Black	The Stop bar code was scanned.
Both	–	STAT	Yellow	Black	A STAT sample appears yellow throughout operation.

## 6.1 STATUS Screen

---

### Sample Scan

This button starts a scan of the sample disk. This button is available if the text on the button is black. If the text on the button is white, then the bar code reader is not available.

### Open Reqs.

Touch this button to access the 'Open requisitions' pop-up window.

## Keyboard Functions

The following is a description of the keys that are active in the STATUS screen.



Confirms an entry in the Operator ID or Disk No. field.



Scrolls down through the four STATUS screens.



Scrolls up through the four STATUS screens.



For the disk system, all samples on the current sample disk and their respective status are printed on a report. Also included are the sample ID, sample disk and position number, sequence number and a list of empty positions.

For the rack system, all samples scanned by the bar code reader and on the C-Line are printed on the report.

Pressing the key a second time stops the analyzer from sending more data to the printer. Printing may not stop immediately.

## 6.2 'Sample Position Status' Pop-up Window

### Introduction

Touching a sample position button on the STATUS screen accesses a window where you can see the sample type, ID, sequence number, disk number or rack number and sample position. It also shows what tests are requested for the sample, results, any flags and when each result is ready.

### 'Sample Position Status' Pop-up Window

An example of the 'Sample Position Status' Pop-up Window for the disk system is shown below.

Stand-by	Operator ID: 47 13:00																																
Inventory	Orders	Results	QC	Status	Util																												
<div><div>Sample Position Status</div><table><thead><tr><th>Test</th><th>Dil.</th><th>Result</th><th>Flags</th><th>Ready</th><th>Type</th><th>Sample</th></tr></thead><tbody><tr><td>TSH</td><td></td><td>12.25</td><td>49</td><td>12:30</td><td>ID</td><td>@123</td></tr><tr><td></td><td></td><td></td><td></td><td></td><td>Seq.</td><td>123</td></tr><tr><td></td><td></td><td></td><td></td><td></td><td>Pos.</td><td>1 - 11</td></tr></tbody></table><div>Close</div></div>						Test	Dil.	Result	Flags	Ready	Type	Sample	TSH		12.25	49	12:30	ID	@123						Seq.	123						Pos.	1 - 11
Test	Dil.	Result	Flags	Ready	Type	Sample																											
TSH		12.25	49	12:30	ID	@123																											
					Seq.	123																											
					Pos.	1 - 11																											

## 6.2 'Sample Position Status' Pop-up Window

An example of the 'Sample Position Status' Pop-up Window for the rack system is shown below.

Stand-by					Operator ID: 47 13:00																												
Inventory	Orders	Results	QC	Status	Util																												
<div><div>Sample Position Status</div><table><thead><tr><th>Test</th><th>Dil.</th><th>Result</th><th>Flags</th><th>Ready</th><th>Type</th><th>Sample</th></tr></thead><tbody><tr><td>TSH</td><td></td><td>12.25</td><td>49</td><td>12:30</td><td>ID : @123</td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td><td>Seq. : 123</td><td></td></tr><tr><td></td><td></td><td></td><td></td><td></td><td>Pos. : 0015 - 3</td><td></td></tr></tbody></table><div>Close</div></div>						Test	Dil.	Result	Flags	Ready	Type	Sample	TSH		12.25	49	12:30	ID : @123							Seq. : 123							Pos. : 0015 - 3	
Test	Dil.	Result	Flags	Ready	Type	Sample																											
TSH		12.25	49	12:30	ID : @123																												
					Seq. : 123																												
					Pos. : 0015 - 3																												

### Data Fields

The following is a description of the fields on the 'Sample Position Status' pop-up window. These fields have no user access; they are for display only.

#### Sample Position Status

##### Test

The assay ordered on the sample.

##### Dil.

The dilution factor selected in the 'Dilution Factor' pop-up window. If no dilution was selected, the field is blank.

##### Result

The test result for the sample. If the software is unable to calculate the result, "No Value" appears in this field.

##### Flags

Any flags generated by the system during result measurement. A list of data flags and their descriptions is found in Chapter 2, Data Alarms – *User's Guide*.

##### Ready

The time when the test result will be ready. Times are not listed for calibrators. The result is displayed and printed as "-----."



## 6.2 'Sample Position Status' Pop-up Window

---

**Type**

The type of sample (i.e., sample, calibrator, control).

**ID**

The identification number of the sample is question.

**Seq.**

The sequence number of the sample.

**Pos.**

The sample disk number and position, or the rack ID and position the sample occupies.

### Window Buttons

The following is a description of the buttons on the 'Sample Position Status' pop-up window.

A green rectangular button with the word "Close" in white text.

Touch this button to close the window and return to the STATUS screen.

## 6.3 Sample Scan 'Confirmation' Pop-up Window

### Introduction

Whenever you initiate a sample scan and are operating in the multiple sample disk mode, you are asked to confirm what disk is on the analyzer. This enables you to verify that the analyzer scans the desired sample disk.

### Sample Scan 'Confirmation' Pop-up Window

An example of the Sample Scan 'Confirmation' pop-up window is shown below.

Stand-by Operator ID: 47 13:00

Inventory Orders Results QC Status Util

Sample Disk Status

1 Empty	2 Empty	3 Empty		
6 Empty	7 Empty	8 Empty		
11 Empty	12 Empty	13 Empty		
16 Empty	17 Empty	18 Empty		
21 Empty	22 Empty	23 Empty	24 Empty	25 Empty
26 Empty	27 Empty	28 Empty	29 Empty	30 Empty

Confirmation

Current disk no. = 1

Resume this S. Scan?

Resume Cancel

Operator ID : 47

Sample ID : 1

Result at :

Sample Scan

Open Reqs.

### Data Fields

The following is a description of the fields on the Sample Scan 'Confirmation' pop-up window. There is no user access to these fields; they are for display only.

#### Current disk no.

The number of the sample disk currently loaded on the analyzer.



*The sample disks are not physically numbered or coded. The disk number in use must be tracked by the operator.*

#### Resume this S. Scan?

You can either resume the sample scan with the current sample disk or you can cancel to enable you to verify the sample disk number.

## 6.3 Sample Scan 'Confirmation' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the Sample Scan 'Confirmation' pop-up window.

A blue rectangular button with the word "Resume" in white text.

Resume

Touch this button if you wish to resume the sample scan with the displayed sample disk. The window closes and returns to the STATUS screen.

A green rectangular button with the word "Cancel" in white text.

Cancel

Touch this button if you wish to cancel operation. The window closes and returns to the STATUS screen.

## 6.4 'Open Requisitions' Pop-up Window

### Introduction

You can delete samples with open requests from the 'Open Requisitions' pop-up window. For the disk system, the samples deleted are those for the sample disk currently displayed on the screen. For the rack system, any requests that are open in the system are deleted. For both systems, this could include downloaded samples (depending upon your interface configuration).

For the disk system, verify that the **Disk No.** field on the STATUS screen indicates the disk for which you want to delete open requests.

### 'Open Requisitions' Pop-up Window

An example of the 'Open Requisitions' pop-up window is shown below. The window appears the same in both disk and rack systems.

Stand-by Operator ID: 47 13:00

Inventory Orders Results QC Status Util

Sample Disk Status

Open Requisitions

Number of open reqs.: 35

Delete Open Cancel

Sample Scan

Open Reqs.

1 Remov	2 Remov	3 Remov		
6 Compl	7 Compl	8 Compl		
11 Compl	12 Incml	13 Compl		
16 Compl	17 Compl	18 Compl		
21 Compl	22 Compl	23 Compl	24 Compl	25 Compl
26 Compl	27 Compl	28 Stop	29 Empty	30 Empty

### Data Fields

The following is a description of the fields on the 'Open Requisitions' pop-up window. There is no user access to these fields; they are for display only.

#### Number of open reqs.

This field displays the number of open requisitions in the system. A "0" (zero) can appear if there are samples in the database with no test selections.

## 6.4 'Open Requisitions' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the 'Open Requisitions' pop-up window.



Touch this button to delete any open requests for the sample disk shown on the window in the system. The window closes and returns the to STATUS screen. Open requisitions can only be deleted when the analyzer is in Stand-by.



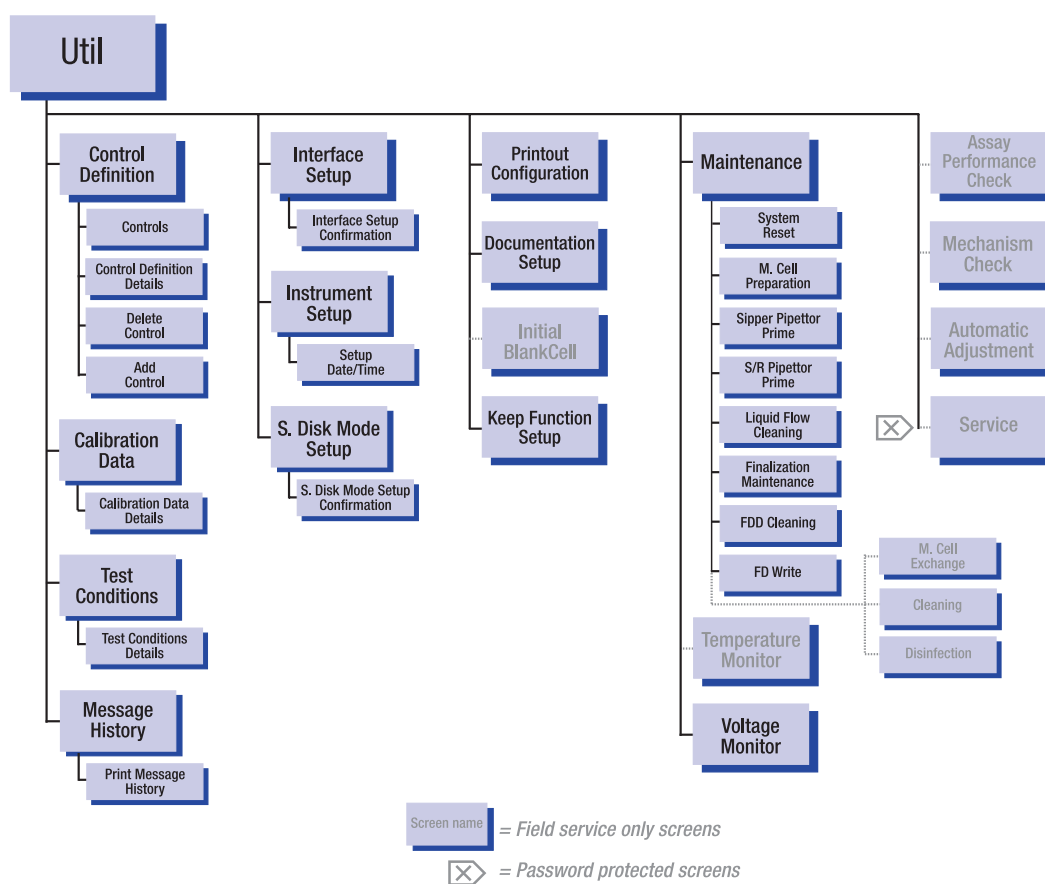
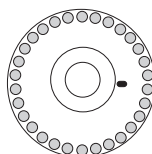
To cancel the operation, touch this button and the 'Open Requisitions' pop-up window closes and returns to the STATUS screen.

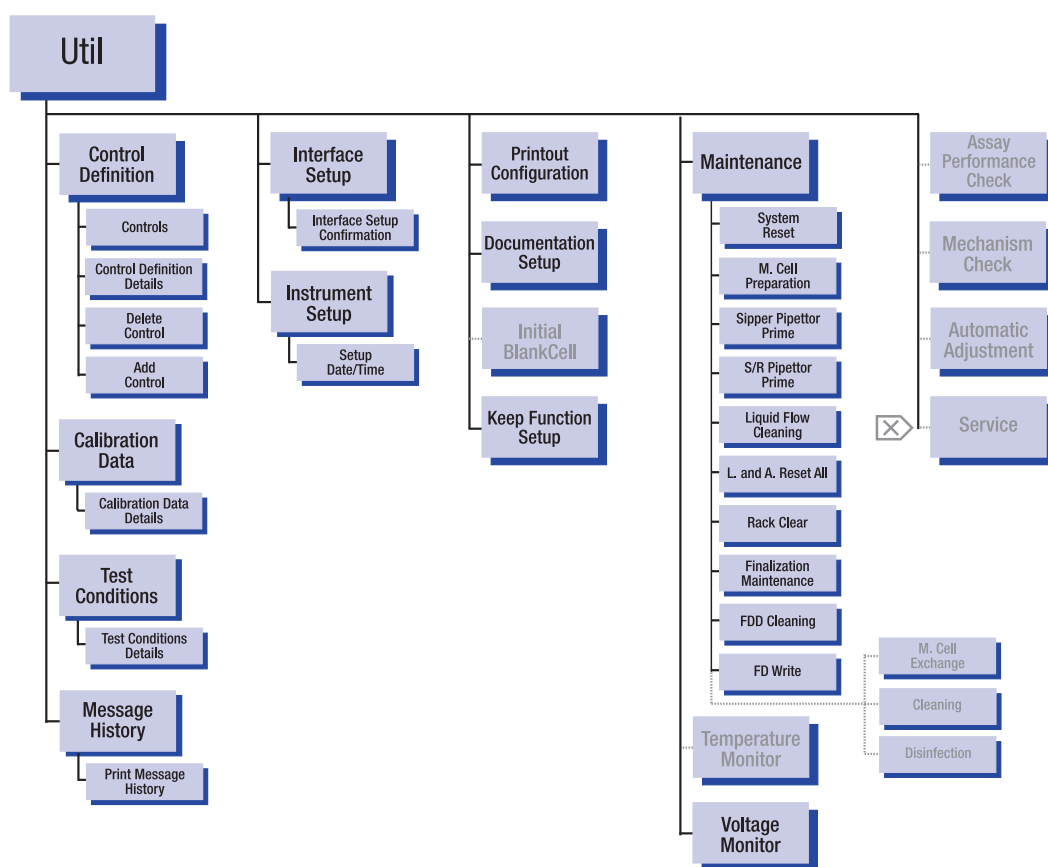
---

## Notes

## Chapter 7

# Util Screen





Screen name = Field service only screens

X = Password protected screens



## 7.1 UTIL Screen

---

### Introduction

On the UTIL (Utility) screen, you can choose among 12 screens for display or entry of sample summary, calibration, analyzer maintenance and others:

- CONTROL DEFINITION: define controls and their test selections
- CALIBRATION DATA: display and evaluate calibration data
- TEST CONDITIONS: display and edit test details
- MESSAGE HISTORY: print alarm message summary
- INTERFACE SETUP: select interface parameters and turn communication ON/OFF
- INSTRUMENT SETUP: specify instrument information such as date and time
- S. DISK MODE SETUP: select single or multiple sample disk options.
- PRINTOUT CONFIGURATION: select single or multiple patient results per page
- DOCUMENTATION SETUP: select upload and printing modes
- KEEP FUNCTION SETUP: setup Keep function choices
- MAINTENANCE: analyzer maintenance and back up data disk
- VOLTAGE MONITOR: monitors the liquid level detection (LLD) voltage of the S/R probe, sipper probe and pressure sensor



Touch the appropriate button to access the corresponding screen. The screens that appear depend upon whether you have a disk or rack system.

The following buttons are primarily utilized by service personnel, but are not password protected:

- INITIAL BLANKCELL
- TEMPERATURE MONITOR
- ASSAY PERF. CHECK
- MECHANISM CHECK
- AUTOMATIC ADJUSTMENT.

There is no need to enter these screens unless you have been instructed to do so by a Roche Diagnostics service representative or by Technical Support.

The remaining button is a screen utilized by service personnel and is password protected and cannot be accessed:

- SERVICE.

## 7.1 UTIL Screen

### UTIL Screen

An example of the UTIL screen for the disk system is shown below.

Stand-by				Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Util
Control Definition	Calibration Data	Test Conditions			Message History
Interface Setup	Instrument Setup	S. Disk Mode Setup			
Printout Configuration	Documentation Setup	Initial BlankCell	Keep Function Setup		
Maintenance	Temperature Monitor	Voltage Monitor			
Assay Perf. Check	Mechanism Check	Automatic Adjustment			Service

An example of the UTIL screen for the rack system is shown below.

Stand-by				Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Util
Control Definition	Calibration Data	Test Conditions			Message History
Interface Setup	Instrument Setup				
Printout Configuration	Documentation Setup	Initial BlankCell	Keep Function Setup		
Maintenance	Temperature Monitor	Voltage Monitor			
Assay Perf. Check	Mechanism Check	Automatic Adjustment			Service

## 7.1 UTIL Screen

---

### Screen Buttons

The following is a description of the buttons on the UTIL screen.

Control  
Definition

Touch this button to access the CONTROL DEFINITION screen.

Calibration  
Data

Touch this button to access the CALIBRATION DATA screen.

Test  
Conditions

Touch this button to access the TEST CONDITIONS screen.

Message  
History

Touch this button to access the MESSAGE HISTORY screen.

Interface  
Setup

Touch this button to access the INTERFACE SETUP screen.

Instrument  
Setup

Touch this button to access the INSTRUMENT SETUP screen.



S. Disk Mode  
Setup

Touch this button to access the S. DISK MODE SETUP screen.

Printout  
Configuration

This button accesses the PRINTOUT CONFIGURATION screen.

Documen-  
tation  
Setup

Touch this button to access the DOCUMENTATION SETUP screen.

## 7.1 UTIL Screen

---

**Initial  
BlankCell**

This button accesses the INITIAL BLANKCELL screen. It is reserved for service personnel.

**Keep  
Function  
Setup**

Touch this button to access the KEEP FUNCTION SETUP screen.

**Maintenance**

Touch this button to access the MAINTENANCE screen.

**Temperature  
Monitor**

This button accesses the TEMPERATURE MONITOR screen. It is reserved for service personnel.

**Voltage  
Monitor**

Touch this button to access the VOLTAGE MONITOR screen.

**Assay  
Perf. Check**

This button accesses the ASSAY PERF. CHECK screen. It is reserved for service personnel.

**Mechanism  
Check**

This button accesses the MECHANISM CHECK screen. It is reserved for service personnel.

**Automatic  
Adjustment**

This button accesses the AUTOMATIC ADJUSTMENT screen. It is reserved for service personnel.

## 7.1 UTIL Screen

---

A green rectangular button with the word "Service" in white text.

This button accesses the SERVICE screen. It is password protected and reserved for service personnel.

A green rectangular button with the word "Util" in white text.

Touch this tab to return to the UTIL screen.

# 7.2 CONTROL DEFINITION Screen

## Introduction

The CONTROL DEFINITION screen allows you to define the test selections for up to 15 controls (i.e., Roche controls that have been scanned into the system or non-Roche controls). When you first access this screen there is no data visible. You must select a control to show data.

## CONTROL DEFINITION Screen

An example of the CONTROL DEFINITION screen is shown below.

Stand-by

Operator ID: 4707:40

Control Definition

Util

Control no. :Lot no. :BC Card ScanControls

Control ID :Exp. date :


## Data Fields

The following is a description of the fields on the CONTROL DEFINITION screen. These fields have no user access; they are for display only.

### Control no.

The assigned control number. For Roche controls, this number is assigned by the software and cannot be altered. The number ranges from 1 to 63. For non-Roche controls this number is user-definable. The available numbers are from 64 to 99.

### Control ID

The control test code.

### Lot no.

The lot number of the control.

## 7.2 CONTROL DEFINITION Screen

---

### **Exp. date**

The control's expiration date. For Roche controls this date is encoded in the control bar code card. For non-Roche controls, this date is entered by the operator.

### **Screen Buttons**

The following is a description of the buttons on the CONTROL DEFINITION screen.

#### **BC Card Scan**

Touch this button to initiate a bar code card scan of either a control or calibrator bar code card. The card must be in the card reading station before touching this button. The card was successfully scanned when you hear the reader beep. Do not remove the card until the Status line reads Stand-by.

This button is available if the text on the button is black. If the text on the button is white, then the bar code reader is not available.

#### **Controls**

Touch this button to access the 'Control Definition' pop-up window.

#### **1 TSH**

Depending upon the control selected, certain tests appear on the screen. Only those tests encoded on the control bar code card or selected by the operator appear here. The buttons appear in order of test number as indicated above the test code.



*If you change the test number for an assay in the 'Test Conditions Details' pop-up window, the test number also changes in the CONTROL DEFINITION screen, but the position held on this screen is as though it is the original test number.*

Touch a test button to select a test to be run on the control. The button turns light blue when selected.

### 7.3 ‘Control Definition’ Pop-up Window

#### Introduction

The ‘Control Definition’ pop-up window is where you select the control for which you want to make test selections. The controls that appear are those that are scanned into the system or added by the operator. The system holds up to 15 Roche and/or non-Roche controls at one time. When the next control is scanned, the controls are replaced on a first in, first out (FIFO) basis.

When you select a control and confirm the entry, the tests available for that control appear on the CONTROL DEFINITION screen.

#### ‘Control Definition’ Pop-up Window

An example of the ‘Control Definition’ pop-up window is shown below.

Stand-by

Operator ID: 47

07:40

Control Definition

Util

Control no. :

Lot no. :

PC TM1  
190475

PC TM2  
190476

PC CARD1  
193301

PC CARD2  
193302

PC U1  
192063

PC U2  
192094

PC TSH  
194383

Delete

Add

OK

Cancel

#### Window Buttons

The following is a description of the buttons on the ‘Control Definition’ pop-up window.



There are 15 control buttons available. Touch the button to select a control. When selected, the button turns light blue.



## 7.3 'Control Definition' Pop-up Window

---

A blue rectangular button with the word "Delete" in white text.

Touch this button to access the 'Delete Control' pop-up window.

A blue rectangular button with the word "Add" in white text.

Touch this button to access the 'Add Control' pop-up window.

A blue rectangular button with the word "OK" in white text.

Touch this button to confirm the control selection. The window closes and returns to the CONTROL DEFINITION screen. The available tests for the control appear.

A green rectangular button with the word "Cancel" in white text.

Touch this button to cancel the control selection. The window closes and returns to the CONTROL DEFINITION screen.

### Keyboard Functions

The following is a description of the keys that are active while in the 'Control Definition' pop-up window.



Press this key to obtain a Control Definition report for the control button that is selected on the screen.

Pressing the key a second time stops the analyzer from sending more data to the printer. Printing may not stop immediately.

## 7.4 'Control Definition Details' Pop-up Window

### Introduction

You must access the 'Control Definition Details' pop-up window in the course of defining Roche or non-Roche controls. Here you can enter or alter the target value and range of the assay and activate the control for use with the assay. For detailed instructions on defining controls, refer to Section 3.10, How To Define Roche (Bar-Coded) Controls and Section 3.11, How To Define Non-Roche (Non-Bar-Coded) Controls – *Tutorial Guide*.

### 'Control Definition Details' Pop-up Window

An example of the 'Control Definition Details' pop-up window is shown below.

### Data Fields

The following is a description of the fields on the 'Control Definition Details' pop-up window. Not all fields have user access. Those that can be accessed are highlighted when touched.

#### Test no., code


The test number of the selected assay is displayed in the field. Next to it is the test code for the assay.

#### Target value, range

For Roche controls, the target value (max. 7 characters) of the control appears in the first field. The range of the control expressed as a percentage of the target value that is then added or subtracted from the previously entered target value.

## 7.4 'Control Definition Details' Pop-up Window

---

To edit an existing control value/range for Roche or non-Roche controls, you must touch each field to activate it before entering values. Press  to confirm.

### **Target lower/upper**

The resulting control range for the assay based upon the data in the `Target value,range` field. There is no access to this field.

### **Unit**

The unit of measure for the assay. There is no access to this field. The unit of measure can be changed in the 'Test Conditions Details' pop-up window/TEST CONDITIONS screen/UTIL folder.

### **Preselection**

Touch "Active" to activate the control. The selection is light blue when active. This activates the assay for the control and allows you to deselect it from the ORDERS screen at a later time, if necessary. If you do not activate the assay, the analyzer does not perform that assay on the control when the control is scanned or selected.

### **Window Buttons**

The following is a description of the buttons on the 'Control Definition Details' pop-up window.



Touch this button to confirm the control definition entries. The window closes and returns to the CONTROL DEFINITION screen.



Touch this button to cancel the control definition entries. The window closes and returns to the CONTROL DEFINITION screen.

### **Keyboard Functions**

The following is a description of the keys that are active while in the 'Control Definition Details' pop-up window.



Confirms an entry in the `Test no.`, `code` or `Target value,range` field.

## 7.5 'Add Control' Pop-up Window

### Introduction

You must access the 'Add Control' pop-up window in the course of defining a non-Roche control. Here you can define the control number, lot number and expiration date of the non-Roche control. For detailed instructions on defining non-Roche controls, refer to Section 3.11, How To Define Non-Roche (Non-Bar-Coded) Controls – *Tutorial Guide*.

### 'Add Control' Pop-up Window

An example of the 'Add Control' pop-up window is shown below.

Stand-by Operator ID: 47 07:40

Control Definition Util

Control no. : 1  
Control ID : PC U1

1 TSH 2 T4 6 FT3 10 E2  
11 TESTO 12 PROG 17 HCGSTAT 18 HCG  
30 CEA 31 AFP

Add Control  
Control no. : 64  
Control ID : Control A  
Lot no. : 56849854  
Exp. year/month : 2000 / 05  
OK Cancel

### Data Fields

The following is a description of the fields on the 'Control Definition Details' pop-up window. Not all fields have user access. Those that can be accessed are highlighted when touched.

#### Control no.

The default for this field is 64. You can use any number from 64 to 99. Touch the field to activate. Press  to confirm entries.

## 7.5 'Add Control' Pop-up Window

---

### Control ID


This field displays the corresponding control identification for the Control number selected in the **Control no.** field. For example, the default Control number of 64 corresponds to "Control A." To use Control B, change the control number to "65." To use Control C, change the control number to "66," etc. There is no user access to this field.

### Lot no.

Type the lot number (max. 8 characters) of the non-Roche control in this field.

Press  to confirm entries.

### Exp.year/month

This field displays the expiration date of the non-Roche control. Touch each field to activate. Press  to confirm entries in each field.

### Window Buttons

The following is a description of the buttons on the 'Add Control' pop-up window.



OK

Touch this button to confirm the control entries. The window closes and returns to the CONTROL DEFINITION screen.



Cancel

Touch this button to cancel the control entries. The window closes and returns to the CONTROL DEFINITION screen.

### Keyboard Functions

The following is a description of the keys that are active while in the 'Add Control' pop-up window.



Confirms an entry in the **Control no.**, **Lot no.** or **Exp.year/month** field.

## 7.6 'Delete Control' Pop-up Window

### Introduction

Access the 'Delete Control' pop-up window to delete a specific Roche or non-Roche control.

### 'Delete Control' Pop-up Window

An example of the 'Delete Control' pop-up window is shown below.

Stand-by Operator ID: 47 07:40

Control Definition Util

Control no. : 1  
Control ID : PC U1

1 TSH 2 T4

11 TESTO 12 PROG

30 CEA 31 AFP

Confirmation  
Delete this control data?

Control no. : 6  
Control ID : PC TM1  
Lot. no. : 190475

OK Cancel

6 FT3 10 E2

17 HCGSTAT 18 HCG

### Data Fields

The following is a description of the fields on the 'Delete Control' pop-up window. These fields have no user access; they are for display only.

#### Delete this control data?

##### Control no.

The control number of the control to be deleted.

##### Control ID

The control identification of the control to be deleted.

##### Lot no.

The lot number of control to be deleted.

## 7.6 'Delete Control' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the 'Delete Control' pop-up window.

A blue rectangular button with the text "OK" in white, centered.

Touch this button to confirm the control deletion. The window closes and returns to the CONTROL DEFINITION screen.

A green rectangular button with the text "Cancel" in white, centered.

Touch this button to cancel the control deletion. The window closes and returns to the CONTROL DEFINITION screen.

## 7.7 CALIBRATION DATA Screen

### Introduction

The CALIBRATION DATA screen shows a list of all reagents with their respective lot numbers and reagent disk position, currently on the analyzer and calibrated. Calibration status is noted by the color of the test button. Green buttons designate successful calibrations. Yellow buttons designate questionable calibrations. Red buttons indicate failed calibrations. Test codes are displayed in ascending test number order.

### CALIBRATION DATA Screen

An example of the CALIBRATION DATA screen is shown below.

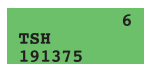
Stand-by		Operator ID: 47			07:40		
Calibration Data					Util		
TSH 191375		T4 189844		FT4 192882		T-UP 192952	T3 191210
E2 192889		TESTO 191909		PROG 194415		LH 192905	FSH 193579
HCGSTAT 194538		CKMBSTAT 190451		TNTSTAT 190450		CEA 195005	CEA 195010
PSA 191898						BC Card Scan	



## 7.7 CALIBRATION DATA Screen

### Screen Buttons

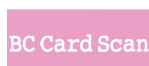
The following is a description of the buttons on the CALIBRATION DATA screen.



Each test button lists the lot number currently in use. Test buttons are sorted first by test number, then by reagent disk position. Touch the button to access the 'Calibration Data Details' pop-up window.

Each button reflects the calibration result by one of the following three colors:

- Green: calibration was successful.
- Yellow: calibration was questionable.
- Red: calibration failed.



Touch this button to initiate a bar code card scan of either a control or calibrator bar code card. The card must be in the card reading station before touching this button. The card was successfully scanned when you hear the reader beep. Do not remove the card until the Status line reads Stand-by.

This button is available if the text on the button is black. If the text on the button is white, then the bar code reader is not available.



Touch this tab to return to the UTIL screen.

### Keyboard Functions

The following is a description of the keys that are active while in the CALIBRATION DATA screen.



If no test buttons are selected, press this key to obtain calibration data reports for all test buttons displayed on the screen.

If a test button is selected (button is light blue), press this key to obtain a calibration data report for the selected assay.

Pressing the key a second time stops the analyzer from sending more data to the printer. Printing may not stop immediately.

## 7.8 'Calibration Data Details' Pop-up Window

### Introduction

The Calibration Data 'Confirmation' pop-up window appears when you touch a test button on the CALIBRATION DATA screen. This window displays the majority of the information contained on the Calibration Data report. From this window releasing you can release or reject a questionable (yellow) calibration. You can only reject a failed (red) calibration.

### 'Calibration Data Details' Pop-up Window

An example of the 'Calibration Data Details' pop-up window for a quantitative assay is shown below.

Stand-by		Operator ID: 47 07:40	
Calibration Data		Util	
<div>Test code : HCGSTAT Lot calibration was successful</div>			
L-Cal date : 05/13/1998		Calibration Quality Criteria	
Reagent pack no. : 718		Lot no. : 194538	
Lot no. : 192927		Missing values -----	
Exp. date : 05/1998		Monotony of curve -----	
Recommended at : 06/12/1998		Calibration factor 1.0	
		Minimum signal -----	
		Deviation of dupl. -----	
		System errors -----	
		Cal. 1.signal 2.signal Target	
		1: 2627 2613 8.98	
		2: 720229 712953 4690	
R-Cal date : 05/13/1998			
Reagent pack no. : 718			
Lot no. : 192927			
Exp. date : 05/1998			
Recommended at : 06/12/1998			
Release		Reject	
OK		Cancel	

## 7.8 'Calibration Data Details' Pop-up Window

An example of the 'Calibration Data Details' pop-up window for a qualitative assay is shown below.

Stand-by		Operator ID: 47		07:40	
Calibration Data			Util		
<b>Test code : A-HBC</b> <b>Lot calibration not successful</b>			<b>Calibration Quality Criteria</b> <b>Lot no. : 194528</b>		
<b>Calib with expired reagent pack</b> <b>L-Cal date :</b> <b>Reagent pack no. :</b> <b>Lot no. :</b> <b>Exp. date :</b> <b>Recommended at :</b>			<b>Missing values</b> ----- <b>Slope</b> OK <b>Min/max signal</b> ----- <b>Minimum accept. difference</b> OK <b>Deviation of dupl.</b> 1- <b>System errors</b> --		
<b>R-Cal date :</b> <b>Reagent pack no. :</b> <b>Lot no. :</b> <b>Exp. date :</b> <b>Recommended at :</b>			<b>Cal. 1.signal 2.signal</b> <b>1: 49042 61171</b> <b>2: 633.8 630.4</b>		
<b>Cutoff : 39207</b> <b>Borderline : 1.00 - 1.00</b>			<b>4</b> <b>9</b> <b>11</b>		
<b>Release</b>			<b>Reject</b>		
<b>OK</b>			<b>Cancel</b>		

### Data Fields

The following is a description of the fields on the 'Calibration Data Details' pop-up window. These fields have no user access; they are for display only.

#### Test code

The test code for the assay selected.

#### Lot calibration was successful

This line by itself states that the calibration was successful and stored in the system as an L-Cal.

#### Reagent pack calib. was successful

This line by itself states that the calibration was successful and stored in the system as an R-Cal.

#### Lot calibration not successful

#### Released as R. pack calib. by system

The calibration was not accepted as an L-Cal, but the system released the calibration as an R-Cal. The reagent pack used for calibration was on the analyzer greater than 24 hours since it was registered. This calibration is only valid for this reagent pack. An L-Cal can only be generated with a reagent pack that has been on the analyzer less than 24 hours since it was registered.

## 7.8 'Calibration Data Details' Pop-up Window

---

### **Lot calibration not successful**

#### **Released as R. pack calib. by operator**

The calibration was not accepted as an L-Cal, but the operator released the calibration as an R-Cal. The initial calibration was questionable, but after further review by the operator, it was determined that the calibration could be released. This calibration is only valid for this reagent pack.

### **R. pack calibration questionable**

#### **Released as R. pack calib by operator**

The attempted R-Cal was questionable and after further review of the calibration quality criteria the calibration was released by the operator. This calibration is only valid for this reagent pack.

### **This calibration cannot be released**

#### **Valid calibration not available**

An L-Cal was attempted on a new assay or new lot of reagent, but because of failure of calibration quality criteria, the calibration failed. Since this is a new assay or new lot of reagent there is no previous calibration data to which to revert.

### **Lot calibration not successful**

This line by itself states that the attempted L-Cal was not successful, but a previous valid calibration exists in the system. The system reverted to the previous calibration to calculate sample results.

### **Reagent pack calib. not successful**

This line by itself states that the attempted R-Cal was not successful, but a previous valid calibration exists in the system. The system reverted to the previous calibration to calculate sample results.

### **Calib with expired reagent pack**

This message can be combined with any other previously described calibration messages with the exception of "Lot Calibration was successful."

### **L-Cal date**

The date of the last valid L-Cal for this lot of reagent.

### **Reagent pack no.**

The unique identifier number of the reagent pack used to generate the L-Cal. Refer to Section 2.1, INVENTORY Screen, for the location of this number on the reagent bar code label.

### **Lot no.**

The lot number of the reagent pack calibrated.

### **Exp. date**

The expiration date of the reagent pack.

## 7.8 'Calibration Data Details' Pop-up Window

---

**Recommended at**

The date at which the next L-Cal is recommended. This date should primarily be used by high volume reagent users (i.e., the reagent pack is used in less than 7 days.)

**R-Cal date**

The date of the last valid R-Cal for this lot of reagent.

**Reagent pack no.**

The identifier number of the reagent pack used to generate the R-Cal.

**Lot no.**

The lot number of the reagent pack used for the last valid R-Cal.

**Exp. date**

The expiration date of the reagent pack.

**Recommended at**

The date at which the next R-Cal is recommended. This date should primarily be used by lower volume reagent users (i.e., the reagent pack is **not** used within 7 days.)

**Calibration Quality Criteria****Lot no.**

The lot number of the assay's CalSet calibrators used for the calibration in question. The lot number is not one of the calibration quality criteria.

**Missing values**

During calibration curve evaluation, the system checks for the completeness of the curve. Therefore, you must have a minimum of n-1 for all calibrator replicates measured (n = total number of calibrator replicates. For any current Elecsys assay, this number totals four.). If all calibrator replicates were sampled with no errors, this field displays 10 dashes. You only see information in the first four, representing Cal 1 and Cal 2. Currently, all Elecsys reagents utilize only two calibrators. This field can accommodate up to five calibrators.

Check to see if any alarms occurred during calibration that may have caused the missing replicate. Accept any questionable calibration according to your laboratory policy.

For further detail on the field display refer to Section 8.9, Calibration Data Report.

**Monotony of curve**

All measured calibrator values must fall in ascending (sandwich or bridging principle) or descending (competition principle) order. This is termed monotony.

## 7.8 'Calibration Data Details' Pop-up Window

---

This field displays five dashes representing up to five calibrators. If either "1" (Cal 1) or "2" (Cal 2) appears in this field, the result is a failed calibration.

Monotony of curve is for **quantitative** assays only.

### **Slope**

All measured calibrator values must fall in ascending (sandwich or bridging principle) or descending (competition principle) order. If this does not occur, or the slope is less than or greater than the slope encoded in the reagent bar code, the calibration fails. The slope of the assay is listed as "OK" or "Not OK."

Slope is for **qualitative** assays only.

### **Calibration factor**

The calibration factor is a curve position check compared to the most recent lot calibration. This field displays a number that represents the calibration factor.

Each lot calibration (L-Cal) utilizes a calibration factor of 1. For all subsequent reagent pack calibrations (R-Cal), a new calibration factor is calculated. The calibration factor is the quotient of the slope of the actual performed calibration and the related stored calibration. ***Calibration factor criterion is only used in validating R-Cals.***

Calibration factor is for **quantitative** assays only. For further detail on the field display refer to Section 8.9, Calibration Data Report.

### **Minimum signal**

The measured signal of the calibrator replicate is below the minimum value. Values are test dependent and are encoded in the reagent bar code. If all calibrator replicates were sampled with no errors, this field displays 10 dashes. You only see information in the first four, representing Cal 1 and Cal 2. Currently, all Elecsys reagents utilize only two calibrators. This field can accommodate up to five calibrators.

Check to see if any alarms occurred during calibration that may have caused a calibrator replicate to have an unacceptable minimum signal. Accept any questionable calibration according to your laboratory policy.

For further detail on the field display refer to Section 8.9, Calibration Data Report.

### **Min/max signal**

The measured signal of the calibrator should fall between the designated minimum and maximum signal. Minimum and maximum signals are test dependent and are encoded in the reagent bar code. If all calibrator replicates were sampled with no errors, this field displays four dashes, representing the calibrator replicates.

Min/max signal is used for **qualitative** assays only. For further detail on the field display refer to Section 8.9, Calibration Data Report.

## 7.8 'Calibration Data Details' Pop-up Window

---

### **Minimum acceptable difference**

The difference between the negative and positive calibrator signal values must be greater than the allowable value limit. The signals are test dependent and are encoded in the reagent bar code. The minimum acceptable difference is listed as "OK" or "Not OK."

Minimum acceptable difference is used for **qualitative** assays only.

### **Deviation of dupl.**

The deviation of duplicate measurements is a check of the signal values for each replicate of a calibrator. If the difference between the duplicate measurements is too great, the appropriate calibrator is flagged. The signal values listed in the `Calibrators` field are the mean value of the duplicate measurements.

This field displays five dashes, representing up to five calibrators. For further detail on the field display refer to Section 8.9, Calibration Data Report.

### **System errors**

A hardware error occurred during a calibrator measurement. This field displays five dashes representing up to five calibrators. If either 1 (Cal 1) or 2 (Cal 2) appear in this field, the result is a failed calibration.

### **Cal.**

#### **1. Signal**

The actual signal level of the first replicate measurement of Cal 1 or Cal 2. The mean of the first and second replicate measurements are used in the calculation of the calibration curve.

#### **2. Signal**

The actual signal level of the second replicate measurement of Cal 1 or Cal 2. The mean of the first and second replicate measurements are used in the calculation of the calibration curve.

### **Target**

The target value of the calibrator. This value is encoded in the CalSet calibrator bar code card.

### **Cutoff**

Qualitative assays are calibrated by a scaling factor, or the cutoff value. The actual cutoff value is calculated by means of the cutoff formula on the basis of at least one high or low calibrator. Each sample receives a scaled result value, the cutoff value, that allows for the classification of samples being reactive or non-reactive (i.e., the cutoff index is greater than or less than 1).

$$\text{Cutoff index} = \frac{\text{measured signal}}{\text{cutoff}}$$

## 7.8 'Calibration Data Details' Pop-up Window

---

### Borderline

For some assays it is possible that in a range around a Cutoff Index = 1, no determination regarding reactive or non-reactive results can be made. This range is called the borderline or borderline area.

Current Elecsys assays have no need for a borderline. Therefore, the upper and lower limit for the borderline area is set to 1. No check is done in this case.


### Window Buttons

The following is a description of the buttons on the 'Calibration Data Details' pop-up window.



Touch this button to release a questionable (yellow) calibration. This button is only available if it is light blue in color. If the button is green, you cannot release the calibration.

Refer to your Calibration Data report for the assay or the data on the window to determine if the calibration can be released. The resulting calibration is an R-Cal.

Sample and QC results obtained prior to pressing  were calculated using the last valid calibration. After releasing the calibration, all subsequent results are calculated using the released R-Cal. Rerun QC samples to determine the validity of the released calibration. In addition, review the QC with "Previous Calibration Used" data alarms to determine if patient samples performed at the same time as the yellow calibration may be acceptable.



*Follow your laboratory protocol regarding questionable or failed calibration results.*



Touch this button to reject a questionable (yellow) calibration or a failed (red) calibration. This button is only available if it is light blue in color. If the button is green, you cannot reject the calibration.

The last valid calibration is used to calculate results for subsequent samples. The calibration should be repeated.



*Follow your laboratory protocol regarding questionable or failed calibration results.*



## 7.8 'Calibration Data Details' Pop-up Window

---

OK

Touch this button to confirm the release or rejection of a questionable (yellow) calibration or failed (red) calibration for the specified assay. The window closes and returns to the CALIBRATION DATA screen.

If the calibration was released, the calibration is released as an R-Cal. If the calibration was rejected, the calibration data was discarded. The system then uses the last valid calibration data, if available, for subsequent testing.

Cancel

Touch this button to cancel the release or rejection of the calibration, close the window and return to the CALIBRATION DATA screen.

Util

Touch this tab to return to the UTIL screen.

### Keyboard Functions

The following is a description of the keys that are active while in the 'Calibration Data Details' pop-up window.



Press this key to obtain a calibration data report for the displayed assay.

Pressing the key a second time stops the analyzer from sending more data to the printer. Printing may not stop immediately.

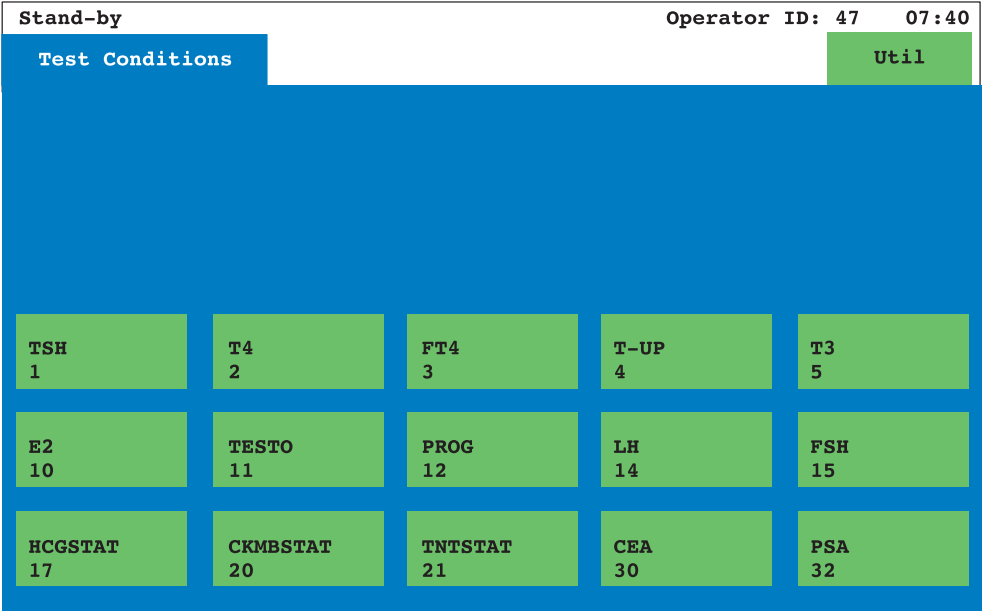
# 7.9 TEST CONDITIONS Screen

## Introduction

The TEST CONDITIONS screen displays buttons on which a test code and a test number are shown. Touch one of these buttons to display the 'Test Conditions Details' pop-up window for the selected assay. Only those assays seen on the last reagent scan appear on the screen.

## TEST CONDITIONS Screen

An example of the TEST CONDITIONS screen is shown below.



## Screen Buttons

The following is a description of the buttons on the TEST CONDITIONS screen.



Each test button lists the test code and test number for the specific assay.



Touch this tab to return to the UTIL screen.

## 7.9 TEST CONDITIONS Screen

---

### Keyboard Functions

The following is a description of the keys that are active while in the TEST CONDITIONS screen.



Press this key to obtain a Test Conditions report for all test buttons currently on the screen.

Pressing the key a second time stops the analyzer from sending more data to the printer. Printing may not stop immediately.

# 7.10 'Test Conditions Details' Pop-up Window

## Introduction

The 'Test Conditions Details' pop-up window is accessed by touching a test button on the TEST CONDITIONS screen. This window provides information on the assay unit of measure, the lower and upper limit of the expected values, instrument factors, and threshold setup.

## 'Test Conditions Details' Pop-up Window

An example of the 'Test Conditions Details' pop-up window is shown below.

Stand-by

Operator ID: 4707:40

Test Conditions

Util

T  
1

E  
1

H  
1

Test code : TSH

Test no.: 1

Unit: uIU/mlmIU/l

Diluent lot no. : 194408

Threshold : 0

Exp. value Lower limit : 0.270

Expected values check: OnOff

Upper limit: 4.20

Daily calib request : OnOff

Instrument factor A : 1.00

Dilution factor :

Instrument factor B : 0.000

OK

Cancel

## Data Entry Fields

The following is a description of the data entry fields on the 'Test Conditions Details' pop-up window. Not all fields allow data entry. Those that can be accessed are highlighted when touched.

### Test code

The assay test code. There is no access to this field.

## 7.10 'Test Conditions Details' Pop-up Window

---

### Test no.

The test number that initially appears in this field is the test number encoded in the reagent bar code label. However, the test number can be user-defined. A number from 1 to 99 may be assigned; each number can only be used once.

The test number is used to sort the test buttons on other screens in the software. The test number that is assigned in this window appears on the status line and in the message history text.



*If you elect to change your test number in this window, be aware that the test number utilized by the host interface remains the same as the one encoded in the reagent bar code (i.e., the number that appears in this window when your software was loaded). If your analyzer is interfaced, we recommend that you do not change the test number.*


### Unit

Up to three units are displayed here. The available units for the assay are encoded in the reagent bar code. The unit that is initially selected is the first unit in the list. However, you can select the desired unit by touching the appropriate text. The selected unit is highlighted in a light blue field. Only those units encoded in the reagent bar code can be utilized by the analyzer.


### Diluent lot no.

The lot number of diluent currently on the analyzer. This field has no user access. If the assay does not require diluent or cannot be diluted, this field is blank.

### Exp. value Lower limit


The lower limit of the expected values encoded in the reagent bar code is found here. This field can be changed to the laboratory specific expected values. Touch the screen to activate the field. Press  to confirm an entry.

### Exp. value Upper limit

The upper limit of the expected values encoded in the reagent bar code is found here. This field can be changed to the laboratory specific expected values. Touch the screen to activate the field. Press  to confirm an entry.

### Instrument factor A

### Instrument factor B

These two fields correspond to slope (A) and intercept (B). Using these factors, results measured by the 2010 can be adjusted to a laboratory specific reference range. The default settings are "1.00" for A and "0.000" for B. Press  to confirm an entry.

## 7.10 'Test Conditions Details' Pop-up Window

---

### **Threshold**

This field allows you to define the number of tests at which point you want notification that the reagent is running low (i.e., INVENTORY button turns yellow; "T" appears in corner). The default for this field is "0."

### **Expected values check**

This field allows you to check the sample result against the expected values for the assay. If "On" is selected, patient results are checked against the expected values, printed on the reports and flagged, if necessary. When "Off" is selected, the Expected value fields are blank and patient results are not checked against the expected values.

The selected choice appears in a light blue field. "On" is the default choice. "Off" is generally used for qualitative tests, but can be selected for any assay.

### **Daily Calib request**

This field allows you to have the INVENTORY screen flag that a daily calibration is necessary. The default for the field is "Off." This field should only be necessary for assays that require daily calibration (e.g., qualitative tests).

### **Dilution factor**

In this field, you can preset a dilution factor for an assay. If you select a dilution factor here, then **all** samples requested for this assay are automatically diluted by the chosen dilution factor. Calibrators and controls are not automatically diluted.

The button functions as a toggle switch and moves through the same dilution choices found in the "Dilution Factor" pop-up window. The field is green if the field cannot be accessed (i.e., the assay does not allow dilution) or if diluent is not on the analyzer.

## **Window Buttons**

The following is a description of the buttons on the 'Test Conditions Details' pop-up window.

A rectangular button with a blue gradient background and the text "OK" in white, centered.

Touch this button to accept entries, close the window and return to the TEST CONDITIONS screen.

A rectangular button with a green gradient background and the text "Cancel" in white, centered.

Touch this button to cancel entries and return to the TEST CONDITIONS screen.

## 7.10 'Test Conditions Details' Pop-up Window

---

### Keyboard Functions

The following is a description of the keys that are active in the 'Test Conditions Details' pop-up window.



Press this key to confirm entries.



Press this key to obtain a Test Conditions report for the test displayed in the pop-up window.

Pressing the key a second time stops the analyzer from sending more data to the printer. Printing may not stop immediately.

## 7.11 MESSAGE HISTORY Screen

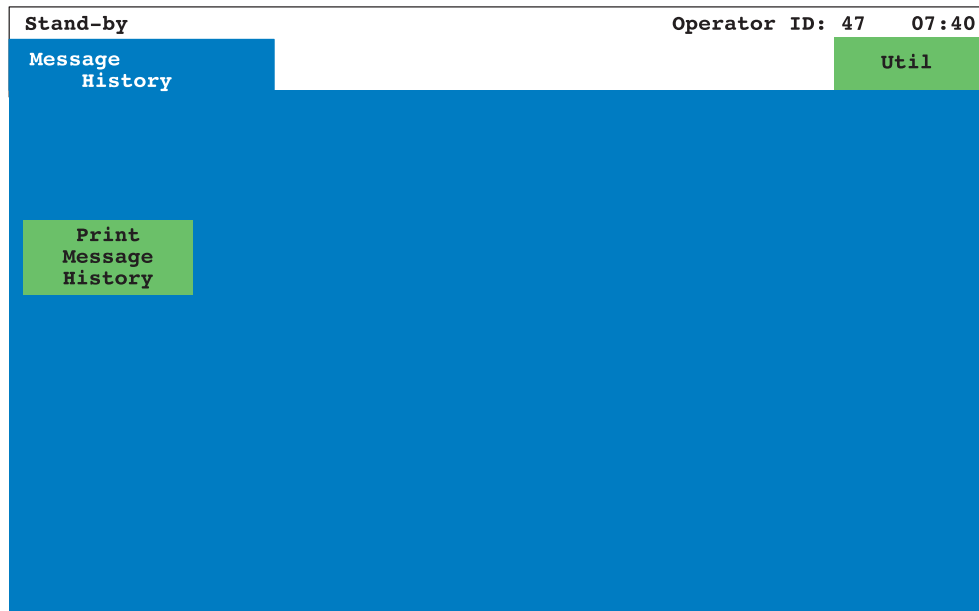
---

### Introduction

The MESSAGE HISTORY screen displays a button to access the summary of alarm messages on the analyzer.

### MESSAGE HISTORY Screen

An example of the MESSAGE HISTORY screen is shown below.



### Screen Buttons

The following is a description of the buttons on the MESSAGE HISTORY screen.



Touch this button to access the 'Print Message History' pop-up window.



Touch this tab to return to the UTIL folder.



## 7.12 'Print Message History' Pop-up Window

### Introduction

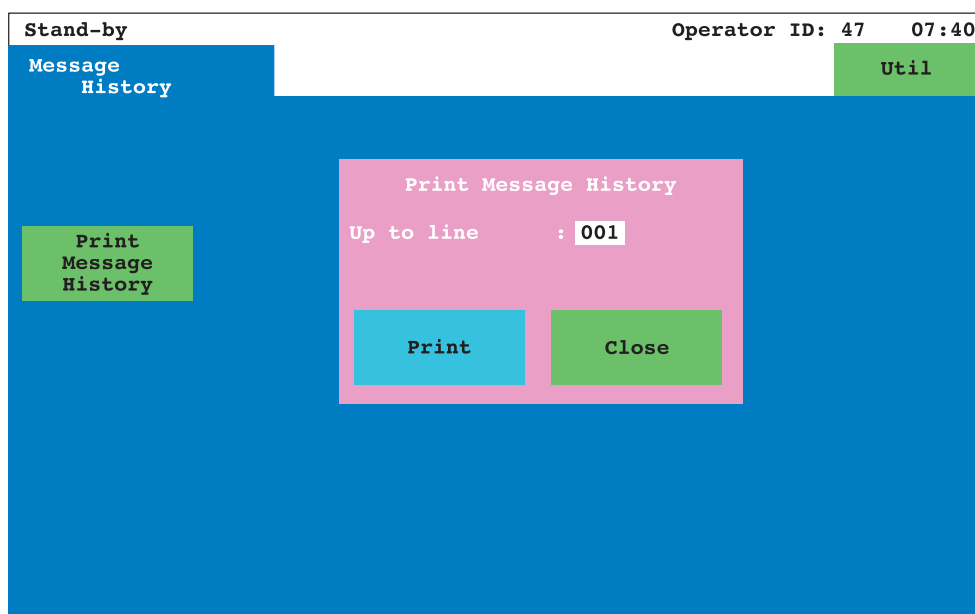
The 'Print Message History' pop-up window allows you to print a list of all alarm messages that occurred on the system. The system holds up to 200 messages. After that, the alarms are replaced on a first in, first out (FIFO) basis.



*The message history cannot be viewed, only printed.*

### 'Print Message History' Pop-up Window


An example of the 'Print Message History' pop-up window is shown below.



### Data Entry Fields

The following is a description of the data entry fields in the 'Print Message History' pop-up window. Touch the field to highlight and activate it.

#### Up to line:

Type the number of messages you want printed. The most recent alarm is printed first. Press  to confirm. You can enter a number from 1 to 200. The default is 1.

## 7.12 'Print Message History' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the 'Print Message History' pop-up window.

A blue rectangular button with the word "Print" in white text.

Touch this button to initiate printing the message history. The window closes and returns to the MESSAGES screen.

A green rectangular button with the word "Close" in white text.

Touching this button closes the window and returns to the MESSAGES screen without printing the message history.

### Keyboard Functions

The following is a description of the keys that are active in the 'Print Message History' pop-up window.



Press this key to confirm entries.

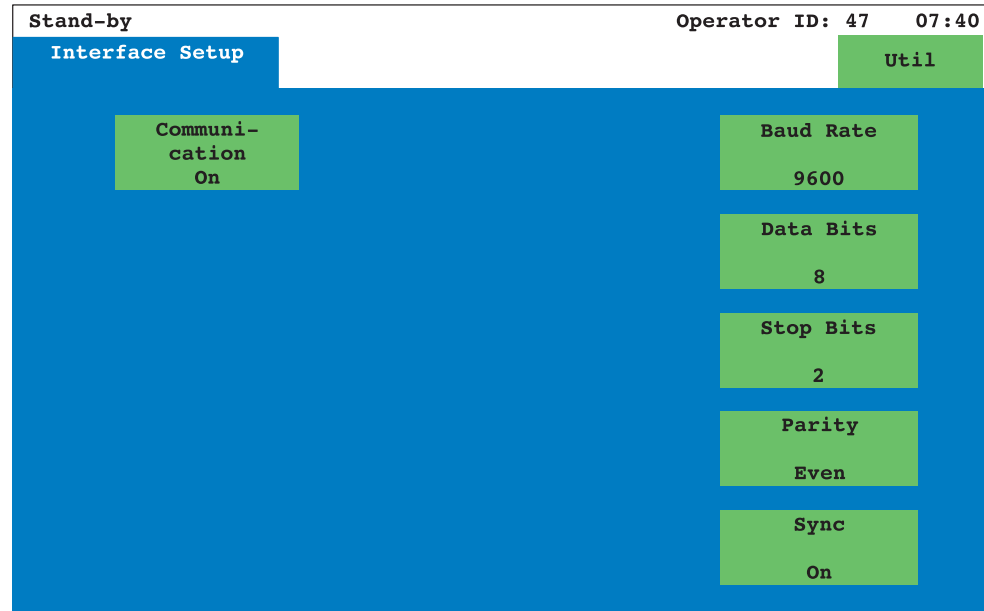
## 7.13 INTERFACE SETUP Screen

### Introduction

On the INTERFACE SETUP screen you can check and set up interface parameters.

### INTERFACE SETUP Screen

An example of the INTERFACE SETUP screen is shown below.

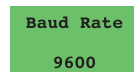


### Screen Buttons

The following is a description of the buttons on the INTERFACE SETUP screen. All buttons for selecting specific parameters act as a toggle switch. The default setting for communication is OFF. You can only make changes to this screen when the analyzer is in Stand-by and communication is OFF.



Touching this button accesses the Interface Setup 'Confirmation' pop-up window. This window lets you turn communication ON or OFF.



Continue to touch this button until the desired baud rate is reached. The baud rate choices are: 2400, 4800, 9600 and 19200. You can select the baud rate only when communication is OFF.

## 7.13 INTERFACE SETUP Screen

---

**Data Bits**  
8

The data bit choices are 7 and 8. You can change the number of data bits only when communication is OFF.

**Stop Bits**  
2

The stop bit choices are 1 and 2. You can change the number of stop bits only when communication is OFF.

**Parity**  
Even

The parity choices are None, Odd and Even. You can change the parity only when communication is OFF.

**Sync**  
On

The synchronization method choices are On and Off. You can change the synchronization method only when communication is OFF.

**Util**

Touch this tab to return to the UTIL folder.

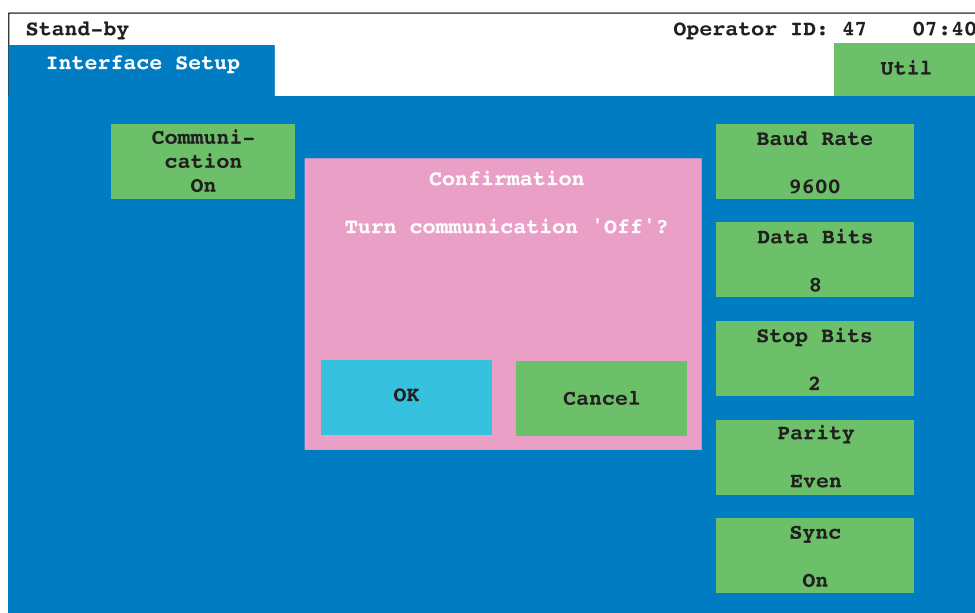
## 7.14 Interface Setup 'Confirmation' Pop-up Window

### Introduction

The Interface Setup 'Confirmation' pop-up window is accessed from the INTERFACE SETUP screen when you wish to enable or disable communication.

### Interface Setup 'Confirmation' Pop-up Window

An example of the Interface Setup 'Confirmation' pop-up window is shown below.



### Window Buttons

The following is a description of the buttons on the Interface Setup 'Confirmation' pop-up window.



Touch to acknowledge your response to the question "Turn communication ON?" or "Turn communication OFF?" The window closes and returns to the INTERFACE SETUP window.



Touch this button to close the window and return to the INTERFACE SETUP screen without changing the communication status.

# 7.15 INSTRUMENT SETUP Screen

## Introduction

In the INSTRUMENT SETUP screen you can check the analyzer information, including the software version, and alter the current date and time.

## INSTRUMENT SETUP Screen

An example of the INSTRUMENT SETUP screen is shown below.

Stand-by	Operator ID: 47		07:40
Instrument Setup			Util
Serial no.	: 093342		
Install date	: 03/16/1998		
Software version	: 03 - 08		
Actual time	: 12:39		
Actual date	: 03/26/1998 (mm/dd/yyyy)		Setup Date/Time
Total test counter	: 8265		
Cell exchange counter	: 8250		

## Data Fields

The following is a description of the data fields on the INSTRUMENT SETUP screen. These fields have no user access; they are for display only.

### Serial no.

The serial number of the analyzer.

### Install date

The software installation date.

### Software version

The version of software currently loaded in the system.

### Actual Time

The current time.

## 7.15 INSTRUMENT SETUP Screen

---

### **Actual Date**

The current date.

### **Total test counter**

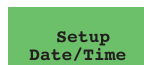
The total cumulative number of tests that have been performed on the analyzer. There is no user access to this field. This number is not reset by reloading software.

### **Cell exchange counter**

This field tracks the number of assays performed on the measuring cell currently on the analyzer. This number is reset to "0" if your service representative installs a new measuring cell.

### **Screen Buttons**

The following is a description of the buttons on the INSTRUMENT SETUP screen.



Touch this button to access the 'Setup Date/Time' pop-up window.



Touch this tab to return to the UTIL folder.

## 7.16 'Setup Date/Time' Pop-up Window

### Introduction

In the 'Setup Date/Time' pop-up window you can set the actual time and date, as well as select the date reporting format you wish to use.

### 'Setup Date/Time' Pop-up Window

An example of the 'Setup Date/Time' pop-up window is shown below.

Stand-by Operator ID: 47 07:40

Instrument Setup Util

Serial no.

Install date

Software version

Actual time

Actual date

Total test count

Cell exchange counter : 8250

Setup of date/time

Actual Time : 12:43  
(24 hour)

Actual date : 03/26/1998  
(mm/dd/yyyy)

Date format : mm/dd/yyyy  
dd.mm.yyyy  
yyyy/mm/dd

OK Cancel

Setup Date/Time

### Data Entry Fields

The following is a description of the data entry fields in the 'Setup Date/Time' pop-up window. Touch the field to highlight and activate it.

#### Actual Time (24 hour)

To change the time, touch the field and type the hours and minutes in a 24-hour format. Press  to confirm the entry.

#### Actual date (mm/dd/yyyy)

To change the date, touch each field and type the month, day and year in the chosen date format. Press  to confirm the entry.

#### Date format

Touch the desired date format to select. The chosen format appears as yellow text on a green background. Choose from "mm/dd/yyyy," "dd.mm.yyyy" or "yyyy/mm/dd."



## 7.16 'Setup Date/Time' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the 'Setup Date/Time' pop-up window.



Touch to acknowledge your date, time and date format selections. The window closes and returns to the INSTRUMENT SETUP window.



Touch this button to close the window and return to the INSTRUMENT SETUP screen without changing the date, time or date format.

### Keyboard Functions

The following is a description of the keys that are active in the 'Setup Date/Time' pop-up window.



Press this key to confirm entries.

# 7.17 S. DISK MODE SETUP Screen

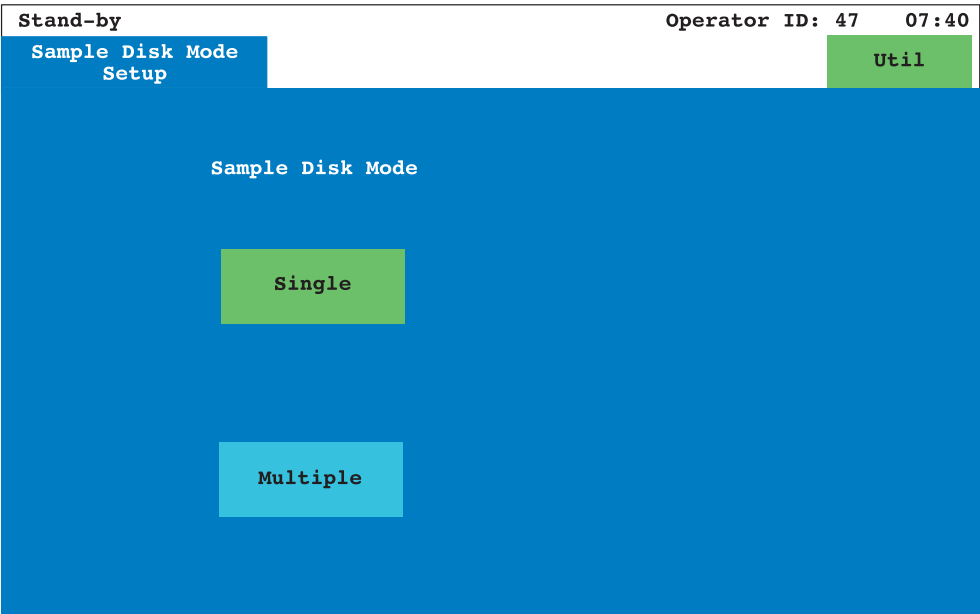
## Introduction

In the S. DISK MODE SETUP screen you can select the mode in which you want to operate your analyzer: single sample disk or multiple sample disks. This choice can only be made when the analyzer is in Stand-by.

This screen only appears on the disk system.

## S. DISK MODE SETUP Screen

An example of the S. DISK MODE SETUP screen for the disk system is shown below.



## Screen Buttons

The following is a description of the buttons on the S. MODE DISK SETUP screen.



Use this button to select the single sample disk mode. Touching this button accesses the S. Mode Disk Setup 'Confirmation' pop-up window.

## 7.17 S. DISK MODE SETUP Screen

---

**Multiple**

Use this button to select the multiple sample disk mode. Touching this button accesses the S. Mode Disk Setup 'Confirmation' pop-up window.

**Util**

Touch this tab to return to the UTIL folder.

## 7.18 S. Disk Mode Setup 'Confirmation' Pop-up Window

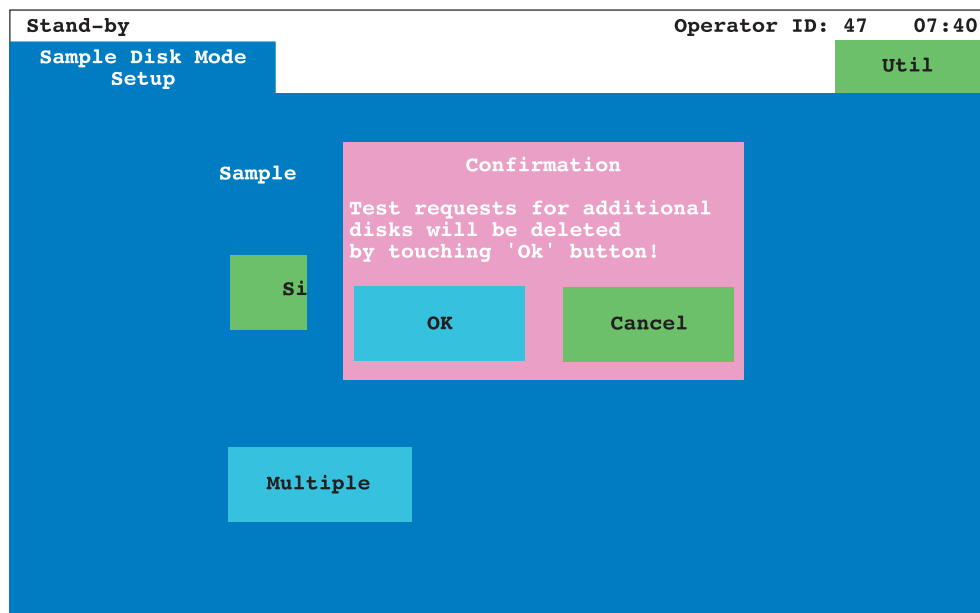
### Introduction

When you touch either of the sample disk mode buttons in the S. DISK MODE SETUP screen the S. Mode Disk Setup 'Confirmation' pop-up window appears. This window verifies that you want to switch disk modes and informs you that all orders on additional disks will be deleted.

This screen only appears on the disk system.

### S. Mode Disk Setup 'Confirmation' Pop-up Window

An example of the S. Mode Disk Setup 'Confirmation' pop-up window is shown below.



### Window Buttons

The following is a description of the buttons on the S. Mode Disk Setup 'Confirmation' pop-up window.



Touch to acknowledge your response to the statement "Test requests for additional disks will be deleted by touching 'OK' button!" The window closes and returns to the S. DISK MODE SETUP screen. Any test requests on additional disks are deleted.

## 7.18 S. Disk Mode Setup 'Confirmation' Pop-up Window

---

Cancel

Touch this button to close the window and return to the S. DISK MODE SETUP screen without changing the sample disk mode or deleting any test requests on additional disks.

Util

Touch this tab to return to the UTIL folder.

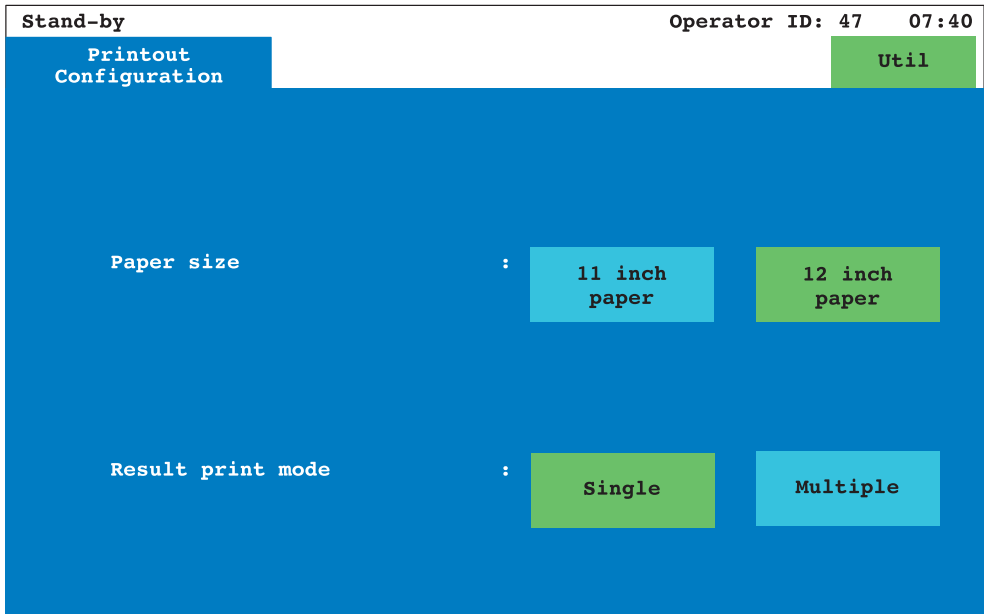
# 7.19 PRINTOUT CONFIGURATION Screen

## Introduction

On the PRINTOUT CONFIGURATION screen you can select how you want patient results to print. You can choose between a single patient's results on a page or multiple patients' results on a page. You can also select the paper size on which your reports print. This choice can only be made when the analyzer is in Stand-by.

## PRINTOUT CONFIGURATION Screen

An example of the PRINTOUT CONFIGURATION screen is shown below.



## Screen Buttons

The following is a description of the buttons on the PRINTOUT CONFIGURATION screen. A choice is selected when the button is light blue. The default print option is "Multiple." The default paper size is "11 inch paper."



Use this button to select 11 inch paper.



Use this button to select 12 inch paper.

## 7.19 PRINTOUT CONFIGURATION Screen

---

**Single**

Use this button to select the single patient report per page.

**Multiple**

Use this button to select the multiple sample reports per page. As many reports that can fit on a page are printed.

**Util**

Touch this tab to return to the UTIL folder.

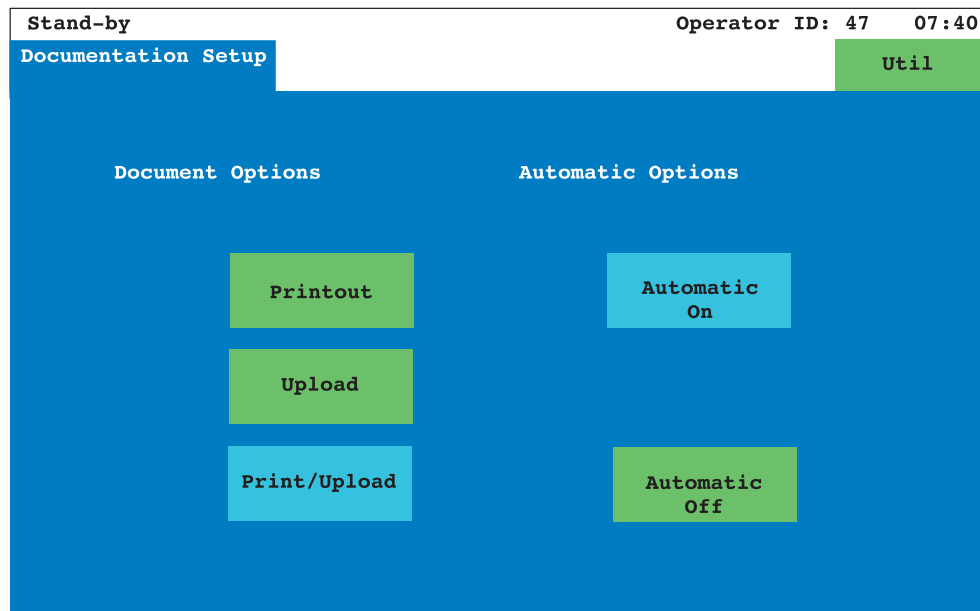
## 7.20 DOCUMENTATION SETUP Screen

### Introduction

The DOCUMENTATION SETUP screen displays and allows you to select the document and automatic options.

### DOCUMENTATION SETUP Screen

An example of the DOCUMENTATION SETUP screen is shown below.



### Screen Buttons

The following is a description of the buttons on the DOCUMENTATION SETUP screen. A button is selected if its color is light blue. You can only make changes in this screen when the analyzer is in Stand-by.

#### Document options

To document a sample, you can print, upload to a host computer or print/upload. The default setting for document options is "Upload."



When this button is selected, samples are documented by printing.



## 7.20 DOCUMENTATION SETUP Screen

---

Upload

When this button is selected samples are documented by an upload to a host computer.

Print/Upload

When this button is selected samples are documented by a combination of printing and uploading.



*You must print AND upload to have the result be considered documented.*

### Automatic options



The automatic options determine whether the selected document option occurs automatically or must be manually initiated. The default setting for automatic options is OFF.

Automatic  
on

If ON is activated, then the document options choice occurs as soon as all of the sample's results are completed.

Automatic  
off

When OFF is selected, to document the sample according to the document option, you must either:

- press  in the RESULTS screen. This documents only the sample displayed on the screen.
- touch the  button on the RESULTS screen. From the pop-up window, select the group of samples to be documented. For additional information, refer to Section 4.3, 'Document Setup' Pop-up Window or Section 2.16, Results – *Tutorial Guide*.

Util

Touch this tab to return to the UTIL folder.

# 7.21 INITIAL BLANKCELL Screen

## Introduction

The INITIAL BLANKCELL screen is reserved for use by Roche Diagnostics service personnel. It is used at analyzer installation and if there is service work done to the measuring cell. There is no need to use this screen unless specifically directed to do so by Roche Diagnostics Service or Technical Support.

## INITIAL BLANKCELL Screen

An example of the INITIAL BLANKCELL screen is shown below.

Stand-by		Operator ID: 47		07:40	
Initial BlankCell		Util			
Initial BlankCell Data			BlankCell Options		
BlankCell procedure date		:	09/03/96		Initial On
BlankCell reagent pack number		:	415		
BlankCell lot no.		:	93		Initial Off
BlankCell parameter(a)		:	65		
(b)		:	1.05		

## 7.22 KEEP FUNCTION SETUP Screen

### Introduction

The KEEP FUNCTION SETUP screen allows you to choose different "Keep" functions - the sample type, the default sample type and the test selection.

### KEEP FUNCTION SETUP Screen

An example of the KEEP FUNCTION SETUP screen is shown below.

Stand-by Operator ID: 47 07:40

Keep Function Setup Util

Keep sample type : On Off

Default sample type : Normal

Keep test selection : On Off

### Data Entry Fields

The following is a description of the data entry fields in the KEEP FUNCTION SETUP screen. Touch the field to highlight and activate it.

#### Keep sample type

This field allows you to choose to keep the same sample type (Normal/Reduced) for patient samples without having to select the choice on the button in the ORDERS screen.

The choices are "On" and "Off." The selected option is light blue. The default selection is "On."

#### Default sample type

This field allows you to choose the default sample type. The field works like a toggle switch. Touch it once to change the sample type from "Normal" to "Reduced." The default selection is "Normal."

## 7.22 KEEP FUNCTION SETUP Screen

---

### **Keep test selection**

This field allows you to keep sample test selections from order to order. For example, if you request T4 and TSH on a sample, after registering the sample, the next order automatically has T4 and TSH requested for it. If a third assay is selected on this sample, then subsequent samples automatically have three assays requested, and so on.

The choices are "On" and "Off." The selected option is light blue. The default selection is "On."

## 7.23 MAINTENANCE Screen

### Introduction

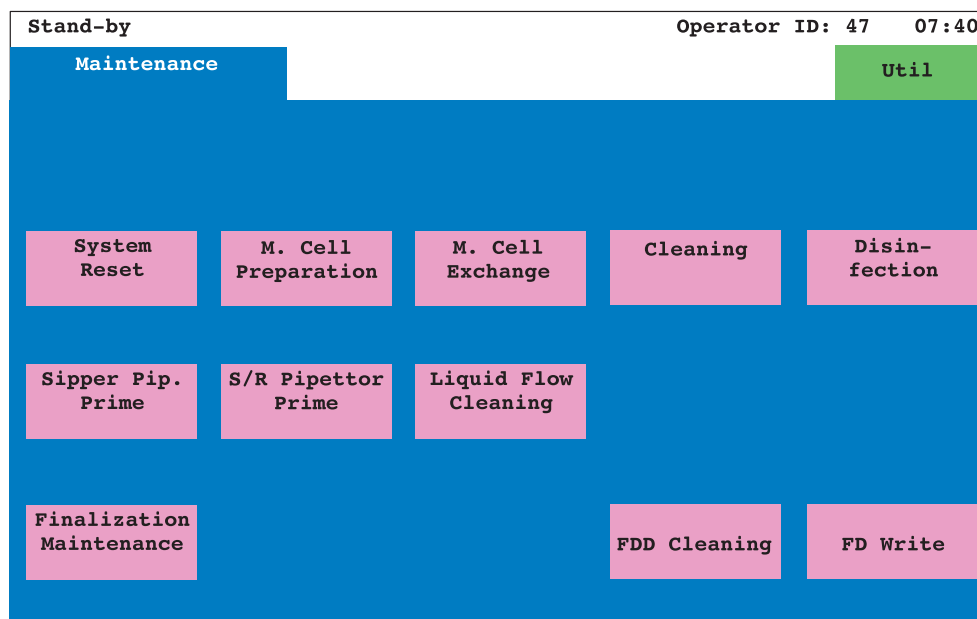
The MAINTENANCE screen lists buttons for various maintenance activities. You can choose from the following functions:

- 'System Reset'
- 'M. Cell Preparation'
- 'Sipper Pip. Prime'
- 'S/R Pipettor Prime'
- 'Liquid Flow Cleaning'
- 'L. and A. Reset All'
- 'Rack Clear'
- 'Finalization Maintenance'
- 'FDD Cleaning'
- 'FD Write'
- *'M. Cell Exchange'*
- *'Cleaning'*
- *'Disinfection.'*

Touch the appropriate button to access the corresponding pop-up window. The italicized choices listed above are reserved for Roche Diagnostics Service.

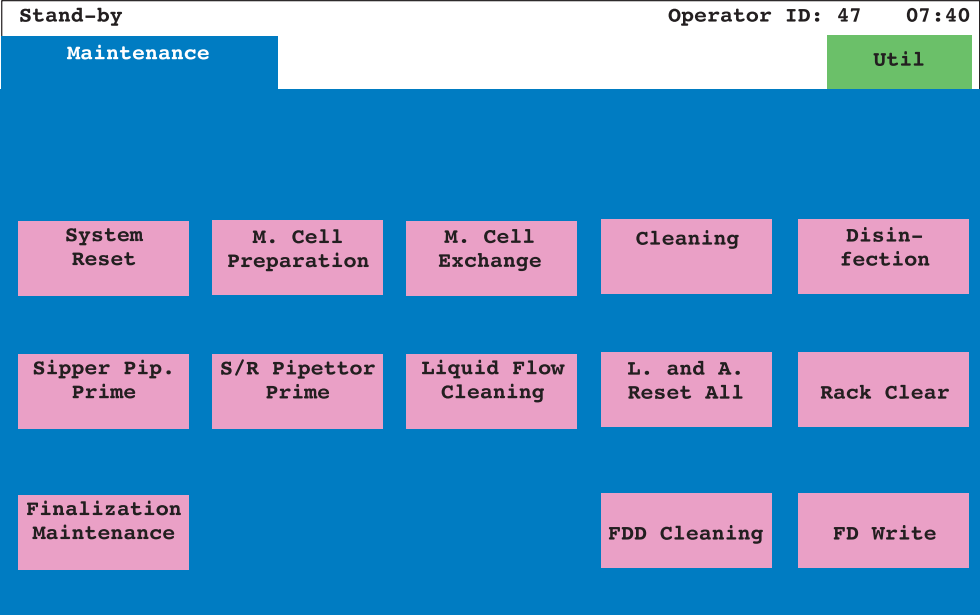
### MAINTENANCE Screen

An example of the MAINTENANCE screen for the disk system is shown below.



# 7.23 MAINTENANCE Screen

An example of the MAINTENANCE screen for the rack system is shown below.

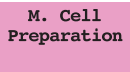


## Screen Buttons

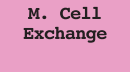
The following is a description of the buttons on the MAINTENANCE screen.



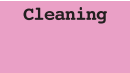
Touch this button to access the 'System Reset' pop-up window.



Touch this button to access the 'M. Cell Preparation' pop-up window. While it is occasionally used by operators, the window is primarily for service personnel.



This button accesses the 'M. Cell Exchange' pop-up window. It is reserved for service personnel.



This button accesses the 'Cleaning' pop-up window. It is reserved for service personnel.

## 7.23 MAINTENANCE Screen

---

**Disin-  
fection**

This button accesses the 'Disinfection' pop-up window. It is reserved for service personnel.

**Sipper Pip.  
Prime**

Touch this button to access the 'Sipper Pipettor Prime' pop-up window.

**S/R Pipettor  
Prime**

Touch this button to access the 'S/R Pipettor Prime' pop-up window.

**Liquid Flow  
Cleaning**

Touch this button to access the 'Liquid Flow Cleaning' pop-up window.

**L. and R.  
Reset All**

Touch this button to access the 'L. and A. Reset All' pop-up window.

**Rack Clear**

Touch this button to access the 'Rack Clear' pop-up window.

**Finalization  
Maintenance**

Touch this button to access the 'Finalization Maintenance' pop-up window.

**FDD Cleaning**

Touch this button to access the 'FDD Cleaning' pop-up window.

**FD Write**

Touch this button to access the 'FD Write' pop-up window.

**Util**

Touch this tab to return to the UTIL screen.

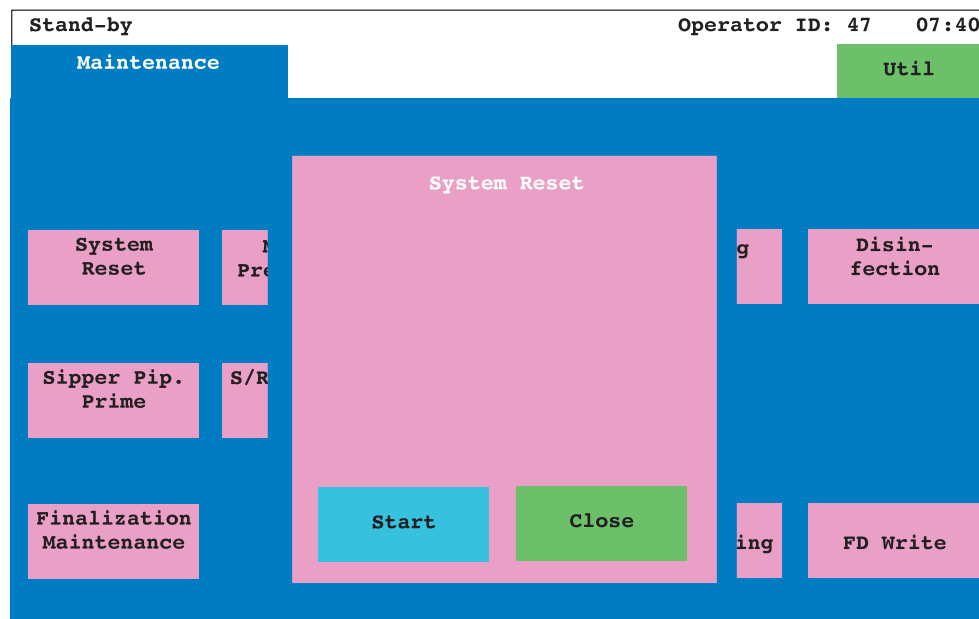
## 7.24 'System Reset' Pop-up Window

### Introduction

The 'System Reset' pop-up window initiates a system reset of the analyzer. All analyzer mechanisms are returned to their home or Stand-by positions. A system reset is often necessary if the analyzer is in a P. Stop or Stop status due to an alarm condition. This button does not cause a reset of any of the line mechanisms on a rack system.

### 'System Reset' Pop-up Window

An example of the 'System Reset' pop-up window is shown below. The window appears the same in both disk and rack systems.



### Window Buttons

The following is a description of the buttons on the 'System Reset' pop-up window.

**Start**

Touch this button to initiate the system reset of the analyzer only. The window closes and returns to the MAINTENANCE screen.

**Close**

Touch this button to close the window without performing the system reset.



## 7.25 'M. Cell Preparation' Pop-up Window

### Introduction

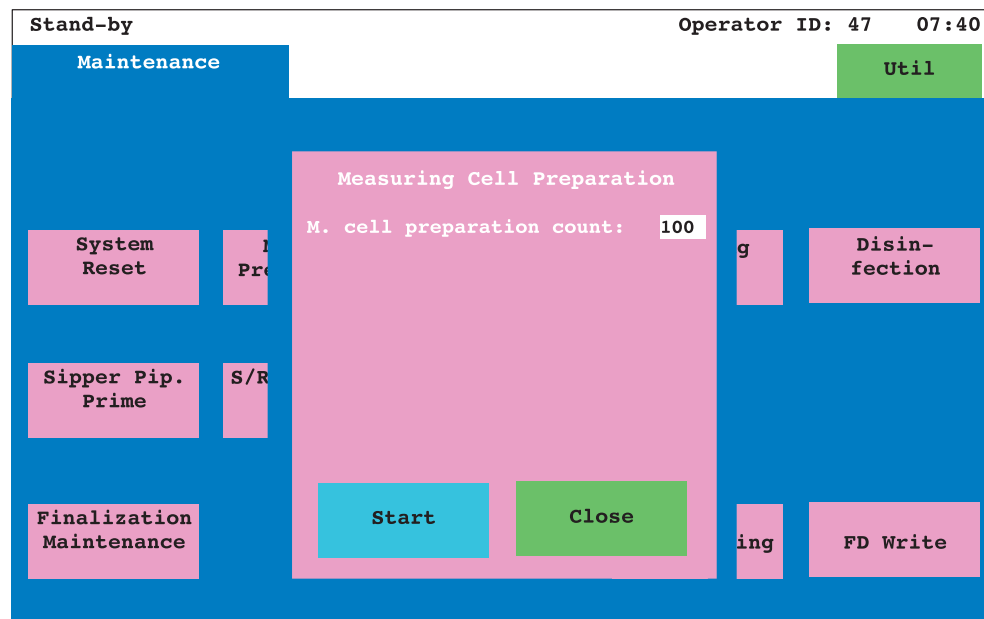
The 'Measuring Cell Preparation' pop-up window is used to prime the measuring cell with ProCell after completing a sipper pipettor prime. The measuring cell prime is necessary to flush the water from the cell and replace it with ProCell.



*Do not use this function for any other purpose unless advised by Roche Diagnostics Service or Technical Support.*

### 'Measuring Cell Preparation' Pop-up Window


An example of the 'Measuring Cell Preparation' pop-up window is shown below. The window appears the same in both disk and rack systems.



### Data Entry Fields

The following is a description of the fields on the 'Measuring Cell Preparation' pop-up window. Touch the field to highlight and activate it.

#### **M. Cell preparation count:**

Type the desired number of priming cycles. Press  to confirm the entry. The allowable range of cycles is 001 to 100. The default is 100 cycles.


## 7.25 'M. Cell Preparation' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the 'Measuring Cell Preparation' pop-up window.

A blue rectangular button with the word "Start" in white text.

Touch this button to initiate the desired priming cycles. The window closes and returns to the MAINTENANCE screen. The button then includes a number equal to the selected priming cycles; this number counts down until the last cycle is completed. You can stop the prime by pressing .

A green rectangular button with the word "Close" in white text.

Touch this button to close the window without performing any priming.

### Keyboard Functions

The following is a description of the keys that are active in the 'Measuring Cell Preparation' pop-up window.

A rectangular key with a black border and the word "Enter" in black text.

Press this key to confirm entries.

A circular key with a black border, a black dot in the center, and the word "Stop" in black text.

Press this key to stop the priming function.

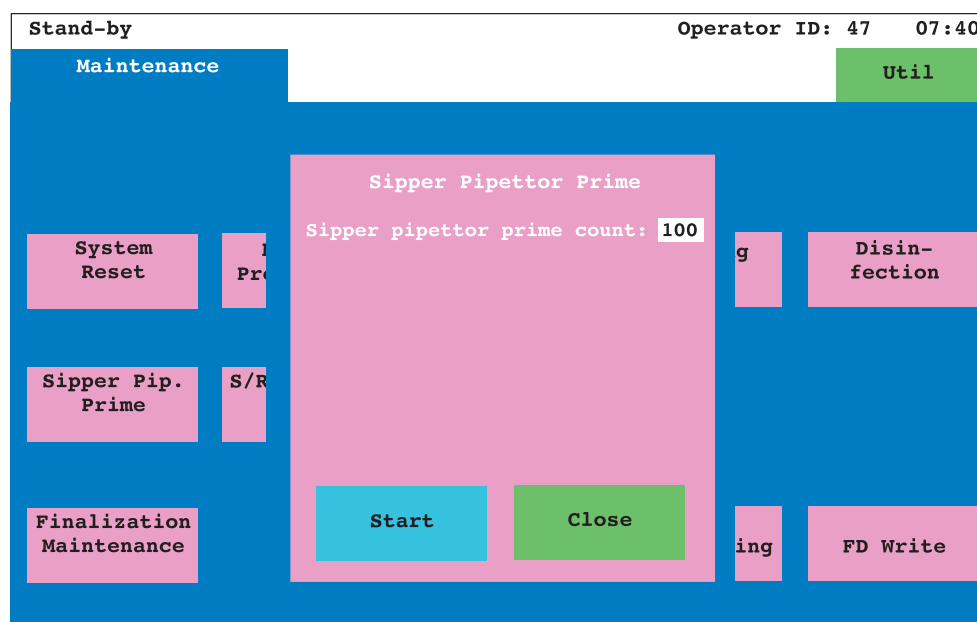
## 7.26 'Sipper Pipettor Prime' Pop-up Window

### Introduction

The 'Sipper Pipettor Prime' pop-up window is used to initiate a priming function of the sipper pipettor. This is necessary after changing pipettor seals.

### 'Sipper Pipettor Prime' Pop-up Window

An example of the 'Sipper Pipettor Prime' pop-up window is shown below. The window appears the same in both disk and rack systems.



### Data Entry Fields

The following is a description of the fields on the 'Sipper Pipettor Prime' pop-up window. Touch the field to highlight and activate it.

#### **Sipper pipettor prime count:**

Type the desired number of priming cycles. Press  to confirm the entry. The allowable range of cycles is 001 to 100. The default is 100 cycles.



*After a sipper pipettor prime, it is necessary to prime the measuring cell with ProCell. Perform a Measuring Cell preparation. Refer to Section 4.14, Replace Pipettor Seals (PM Visit) – User's Guide.*



## 7.26 'Sipper Pipettor Prime' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the 'Sipper Pipettor Prime' pop-up window.

A blue rectangular button with the word "Start" in white text.

Touch this button to initiate the desired priming cycles. The window closes and returns to the MAINTENANCE screen. The  button then includes a number equal to the selected priming cycles; this number counts down until the last cycle is completed. You can stop the prime by pressing .

A green rectangular button with the word "Close" in white text.

Touch this button to close the window without performing any priming.

### Keyboard Functions

The following is a description of the keys that are active in the 'Sipper Pipettor Prime' pop-up window.



Press this key to confirm entries.



Press this key to stop the priming function.

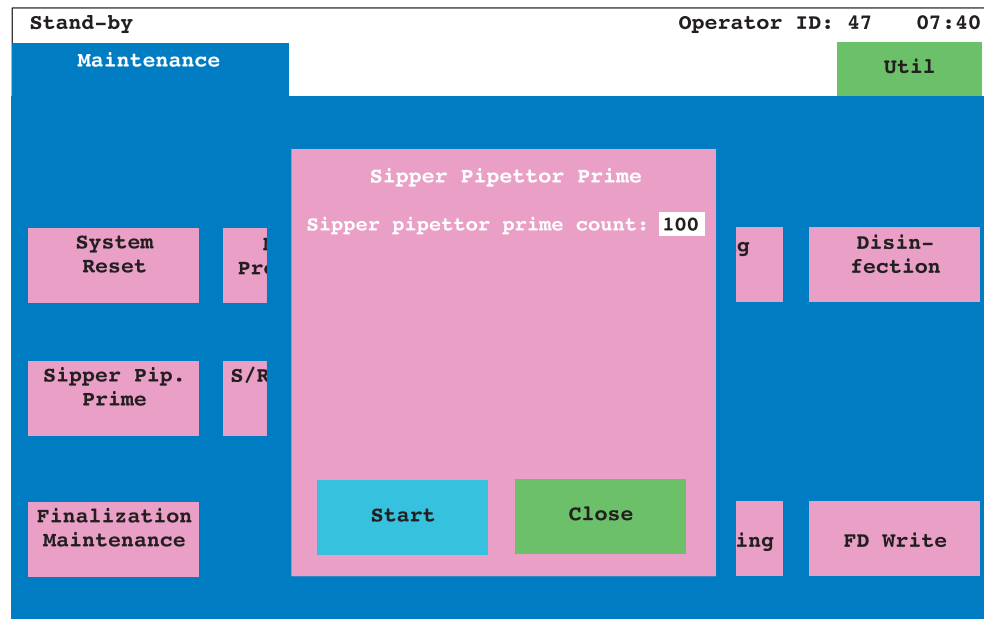
## 7.27 'S/R Pipettor Prime' Pop-up Window

### Introduction

The 'S/R Pipettor Prime' pop-up window is used to initiate a priming function of the S/R pipettor. This is necessary after changing pipettor seals.

### 'S/R Pipettor Prime' Pop-up Window

An example of the 'S/R Pipettor Prime' pop-up window is shown below. The window appears the same in both disk and rack systems.



### Data Entry Fields

The following is a description of the fields on the 'S/R Pipettor Prime' pop-up window. Touch the field to highlight and activate it.

#### S/R pipettor prime count:

Type the desired number of priming cycles. Press  to confirm the entry. The allowable range of cycles is 001 to 100. The default is 100 cycles.



## 7.27 'S/R Pipettor Prime' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the 'S/R Pipettor Prime' pop-up window.

A blue rectangular button with the word "Start" in white text.

Touch this button to initiate the desired priming cycles. The window closes and returns to the MAINTENANCE screen. The  button then includes a number equal to the selected priming cycles; this number counts down until the last cycle is completed. You can stop the prime by pressing .

A green rectangular button with the word "Close" in white text.

Touch this button to close the window without performing any priming.

### Keyboard Functions

The following is a description of the keys that are active in the 'S/R Pipettor Prime' pop-up window.



Press this key to confirm entries.



Press this key to stop the priming function.

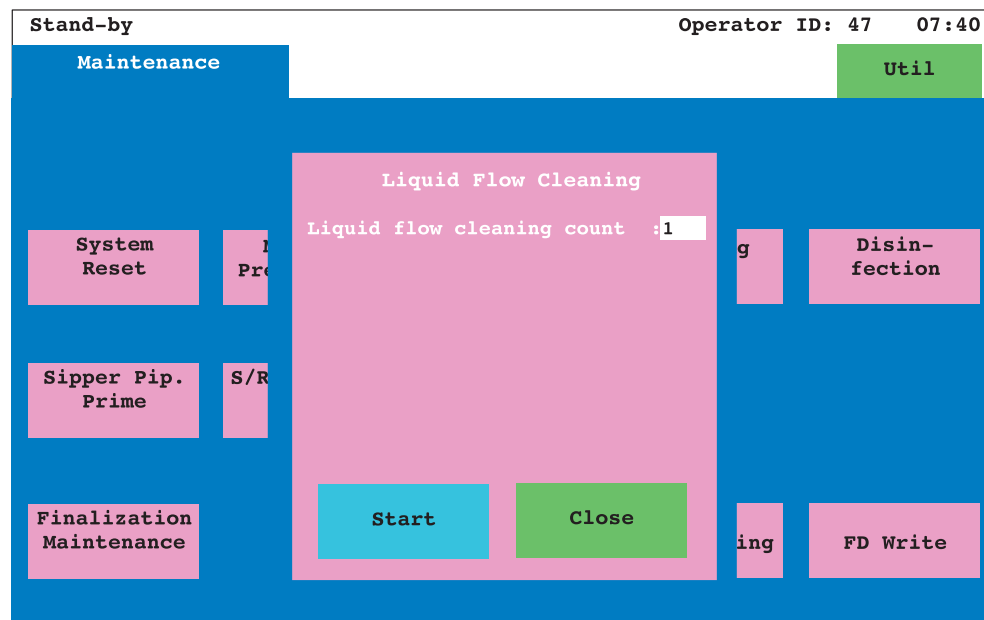
## 7.28 'Liquid Flow Cleaning' Pop-up Window

### Introduction

The 'Liquid Flow Cleaning' pop-up window is used to initiate the liquid flow cleaning procedure. Perform this maintenance procedure every two weeks to maintain the integrity of the measuring cell. For detailed instructions on the Liquid Flow Cleaning procedure, refer to Section 4.7, Perform Liquid Flow Cleaning – *User's Guide*.

### 'Liquid Flow Cleaning' Pop-up Window

An example of the 'Liquid Flow Cleaning' pop-up window is shown below. The window appears the same in both disk and rack systems.



### Data Entry Fields

The following is a description of the fields on the 'Liquid Flow Cleaning' pop-up window. Touch the field to highlight and activate it.

#### Liquid flow cleaning count:

Type the desired number of cleaning cycles. Press  to confirm the entry. The allowable range of cycles is 001 to 100. The default is 1 cycle.



## 7.28 'Liquid Flow Cleaning' Pop-up Window

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### Window Buttons

The following is a description of the buttons on the 'Liquid Flow Cleaning' pop-up window.

A blue rectangular button with the word "Start" in white text.

Touch this button to initiate the desired cleaning cycles. The window closes and returns to the MAINTENANCE screen. The  button then includes a number equal to the selected cleaning cycles; this number counts down until the last cycle is completed. You can stop the cleaning by pressing .



*If you stop the procedure before it is completed, you must restart the procedure or initiate an M. Cell Preparation to flush the SysClean from the measuring cell.*

A green rectangular button with the word "Close" in white text.

Touch this button to close the window without performing any cleaning.

### Keyboard Functions

The following is a description of the keys that are active in the 'Liquid Flow Cleaning' pop-up window.



Press this key to confirm entries.



Press this key to stop the cleaning function.



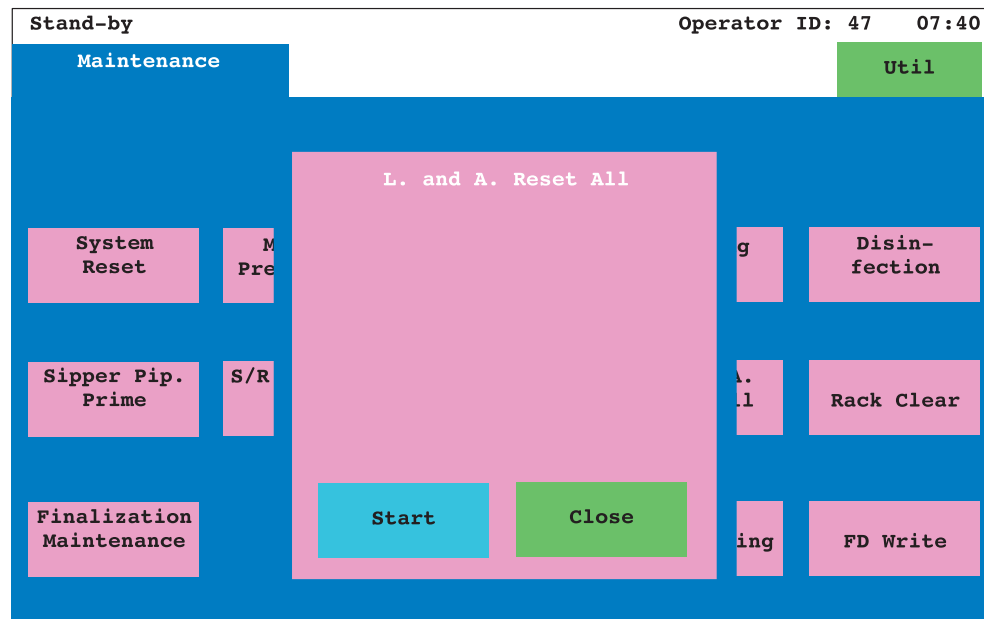
## 7.29 'L. and A. Reset All' Pop-up Window

### Introduction

The 'L. and A. Reset All' pop-up window initiates a complete system and line reset for the rack analyzer. A-, B- and C-Line, as well as all analyzer mechanisms are returned to their home or Stand-by positions. An L. and A. Reset All is often necessary if the analyzer is in a P. Stop or Stop status due to an alarm condition. This button is only available on a rack system.

### 'L. and A. Reset All' Pop-up Window

An example of the 'L. and A. Reset All' pop-up window for the rack system is shown below.



### Window Buttons

The following is a description of the buttons on the 'L. and A. Reset All' pop-up window.



Touch this button to initiate the line and system reset of the rack analyzer. The window closes and returns to the MAINTENANCE screen.



Touch this button to close the window without performing the reset.

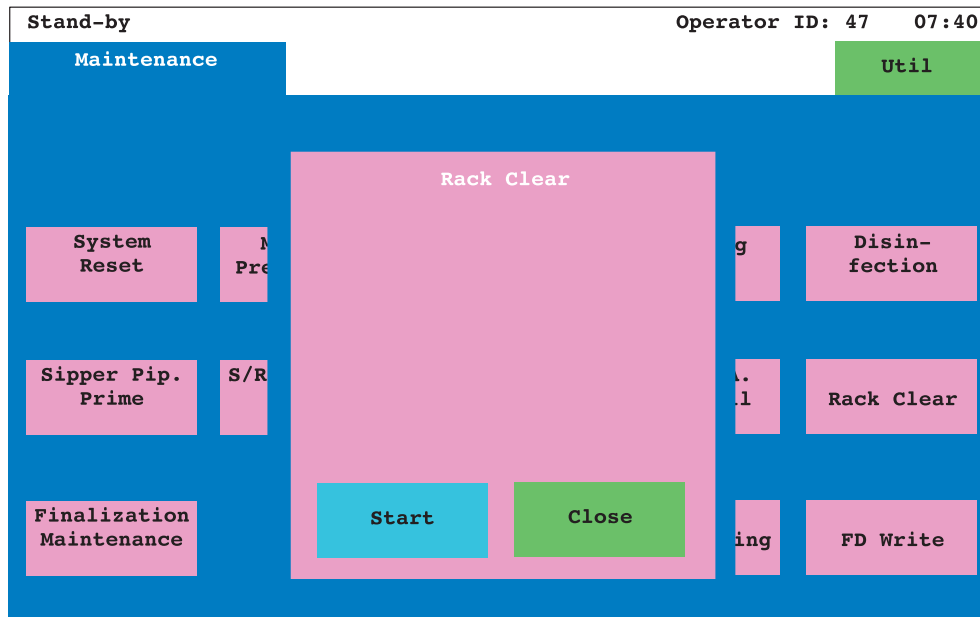
## 7.30 'Rack Clear' Pop-up Window

### Introduction

The 'Rack Clear' pop-up window clears the B-Line of any racks and transfers them to the C-Line. This window is only available for a rack system.

### 'Rack Clear' Pop-up Window

An example of the 'Rack Clear' pop-up window for the rack system is shown below.



### Window Buttons

The following is a description of the buttons on the 'Rack Clear' pop-up window.

**Start**



Touch this button to clear any racks from the B-Line. The window closes and returns to the MAINTENANCE screen.

**Close**

Touch this button to close the window without clearing the B-Line.

## 7.31 'Finalization Maintenance' Pop-up Window

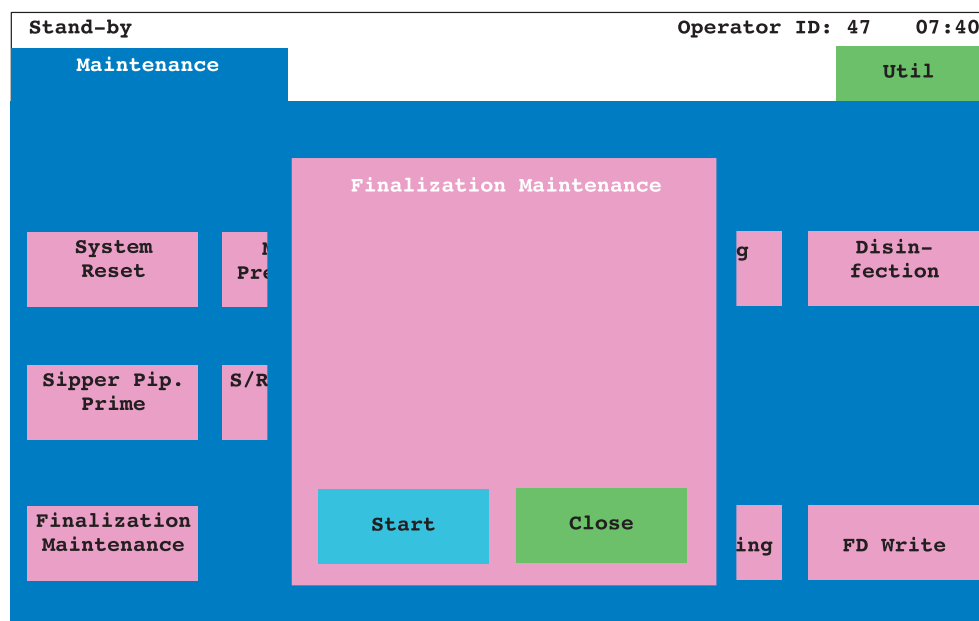
### Introduction

The 'Finalization Maintenance' pop-up window initiates the daily maintenance procedure of finalization maintenance. Finalization is the analyzer status that occurs between the time when the analyzer stops pipetting samples (S. Stop or R. Stop) and Stand-by. Pressing  when the analyzer status is S. Stop or R. Stop bypasses finalization and puts the analyzer directly into Stand-by. If the Elecsys 2010 analyzer does not automatically enter finalization status during the course of the day (i.e., continuously loading the analyzer or pressing ) , you must initiate finalization maintenance.

Finalization allows the analyzer to stand unused for several hours (e.g., overnight). The system is primed with water, the measuring cell is filled with ProCell and the sipper probe is cleaned with water.

### 'Finalization Maintenance' Pop-up Window

An example of the 'Finalization Maintenance' pop-up window is shown below. The window appears the same in both disk and rack systems.



## 7.31 'Finalization Maintenance' Pop-up Window

---

### Window Buttons

The following is a description of the buttons on the 'Finalization Maintenance' pop-up window.

A blue rectangular button with the word "Start" in white text.

Touch to start the finalization maintenance procedure. The window closes and returns to the MAINTENANCE screen.

A green rectangular button with the word "Close" in white text.

Touch this button to close the window and return to the MAINTENANCE screen without starting the finalization maintenance procedure.

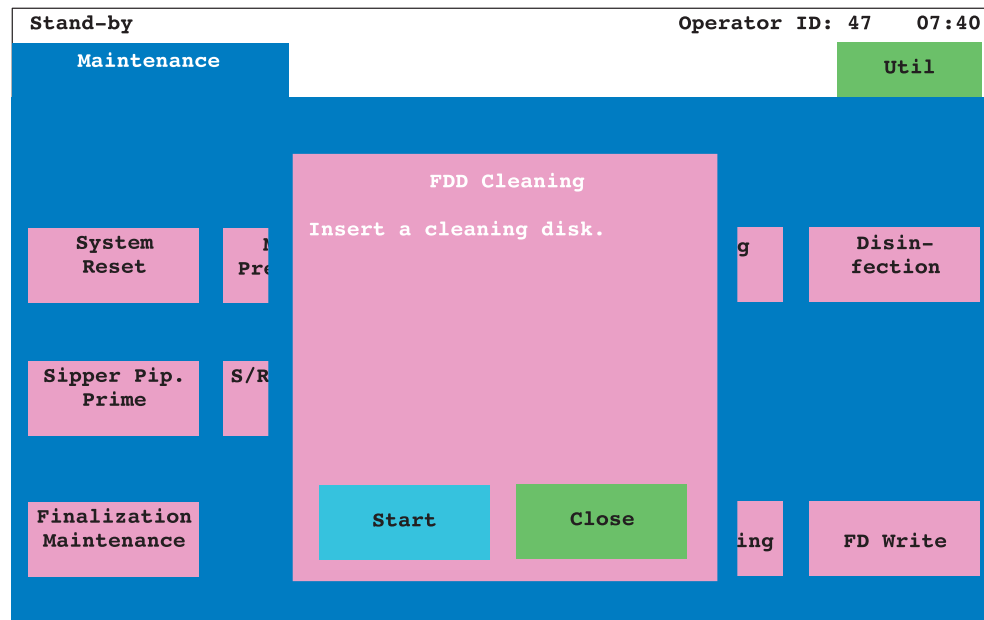
## 7.32 'FDD Cleaning' Pop-up Window

### Introduction

The 'FDD Cleaning' pop-up window is used to clean the floppy disk drive. This maintenance procedure is performed every month.

### 'FDD Cleaning' Pop-up Window

An example of the 'FDD Cleaning' pop-up window is shown below. The window appears the same in both disk and rack systems.



### Window Buttons

The following is a description of the buttons on the 'FDD Cleaning' pop-up window. For detailed instructions on this procedure, refer to Section 4.8, Clean Floppy Disk Drive – *User's Guide*.



Touch to begin the disk cleaning. The window closes and returns to the MAINTENANCE screen.



**Verify the drive is not active (green light is on) before you remove the data disk.**

## 7.32 'FDD Cleaning' Pop-up Window

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*Failure to replace the data disk with the cleaning disk results in the LOSS OF ALL DATA ON THE DATA DISK.*

Close

Touch this button to close the window and return to the MAINTENANCE screen without copying files from analyzer memory.

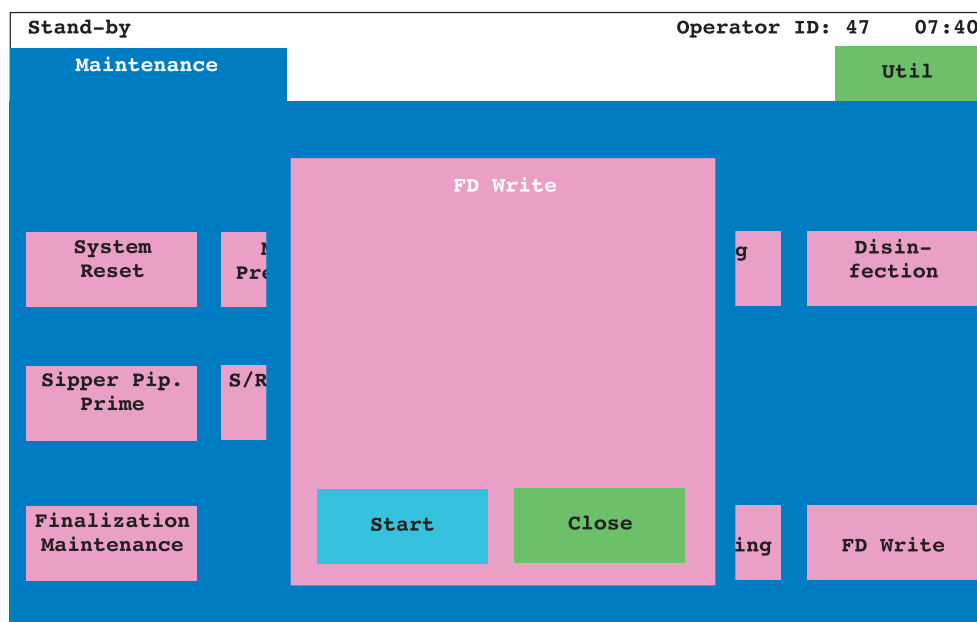
## 7.33 'FD Write' Pop-up Window

### Introduction

The 'FD Write' pop-up window is used to write data files that are currently in analyzer memory onto a PC-formatted data disk.

### 'FD Write' Pop-up Window

An example of the 'FD Write' pop-up window is shown below. The window appears the same in both disk and rack systems.



### Window Buttons

The following is a description of the buttons on the 'FD Write' pop-up window.



Touch to begin copying files from analyzer memory onto a PC-formatted disk to create a copy of the data disk. The window closes and returns to the MAINTENANCE screen.



Touch this button to close the window and return to the MAINTENANCE screen without copying files from analyzer memory.

## 7.34 MAINTENANCE Windows for Service Personnel

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### Introduction

Three of the buttons on the MAINTENANCE screen are reserved for service personnel. They are as follows:

- |                     |   |
|---------------------|---|
| 'M. Cell Exchange:' | This window is for flushing the measuring cell flow path and draining it. |
| 'Disinfection:'     | This window is for washing the measuring cell flow path.                  |
| 'Cleaning:'         | This window is for cleaning the sipper system flowpath.                   |

DO NOT perform these functions unless advised by Roche Diagnostics Service.



## 7.35 TEMPERATURE MONITOR Screen

### Introduction

The TEMPERATURE MONITOR screen is reserved for use by Roche Diagnostics service personnel. It is mainly used to check temperatures of the temperature controlled units on the analyzer. These components are the detection unit (measuring cell), incubator, reagent disk and system reagent compartments (ProCell and CleanCell). There is no need to use this screen unless specifically directed to do so by Roche Diagnostics Service or Technical Support.

### TEMPERATURE MONITOR Screen

An example of the TEMPERATURE MONITOR screen is shown below.

Stand-by		Operator ID: 47 07:40			
Temperature Monitor		Util			
		Ambient Temp.	Temperature	Target Temp.	Control Param.
Detection Unit	:	-----	27.3	27.3	-0.2
Incubator	:	-----	37.0	37.0	1.7
Reagent	:	23.4	18.2	17.7	-0.9
PC/CC	:	26.1	27.8	28.0	0.3
Unit: Degrees Centigrade					

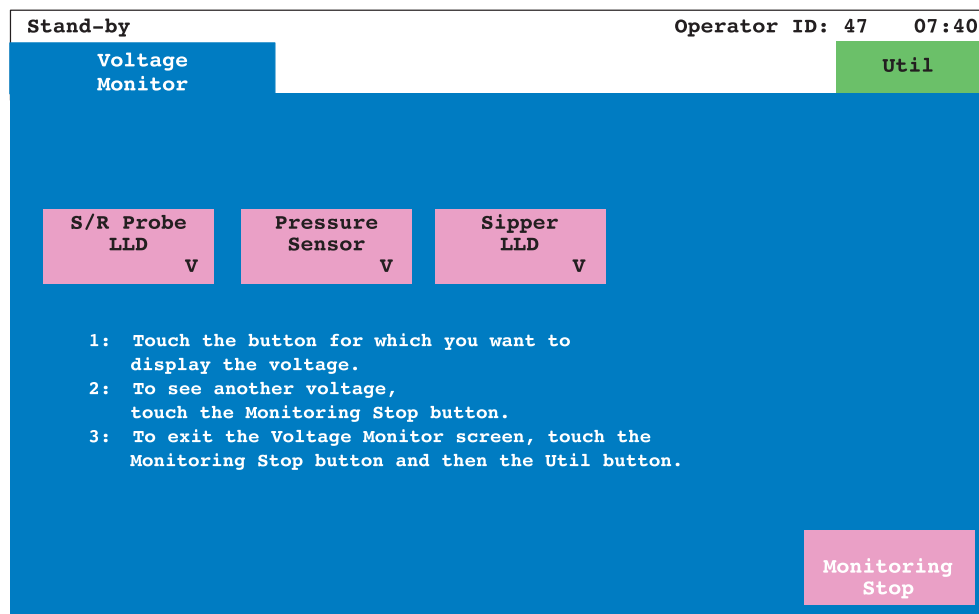
## 7.36 VOLTAGE MONITOR Screen

### Introduction

In the VOLTAGE MONITOR screen you can check the LLD voltages of the S/R probe, the pressure sensor for clot detection and the sipper probe. If you are experiencing certain LLD instrument alarms, you may be instructed to use this screen. Voltages can only be checked while the analyzer is in Stand-by.

### VOLTAGE MONITOR Screen

An example of the VOLTAGE MONITOR screen is shown below.



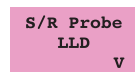
### Data Fields

There are no data fields on this screen; the text on the screen are instructions on how to check the desired voltage.

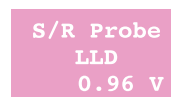
## 7.36 VOLTAGE MONITOR Screen

### Screen Buttons

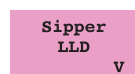
The following is a description of the buttons on the VOLTAGE MONITOR screen.



Use this button to check the LLD voltage of the S/R probe. When active, the text on the button changes from black to white and displays the current voltage to the left of the "V." Refer to the specific instrument alarm remedy column in Chapter 3, Instrument Alarms – *User's Guide*, for the recommended voltage.



Use this button to check the clot detection voltage of the S/R probe. When active, the text on the button changes from black to white and displays the current voltage to the left of the "V." Refer to the specific instrument alarm remedy column in Chapter 3, Instrument Alarms – *User's Guide*, for the recommended voltage.



Use this button to check the LLD voltage of the sipper probe. When active, the text on the button changes from black to white and displays the current voltage to the left of the "V." Refer to the specific instrument alarm remedy column in Chapter 3, Instrument Alarms – *User's Guide*, for the recommended voltage.



Touch this button when you want to stop monitoring the desired voltage. When voltages are being monitored, the text on the button is black.



Touch this tab to return to the UTIL folder.

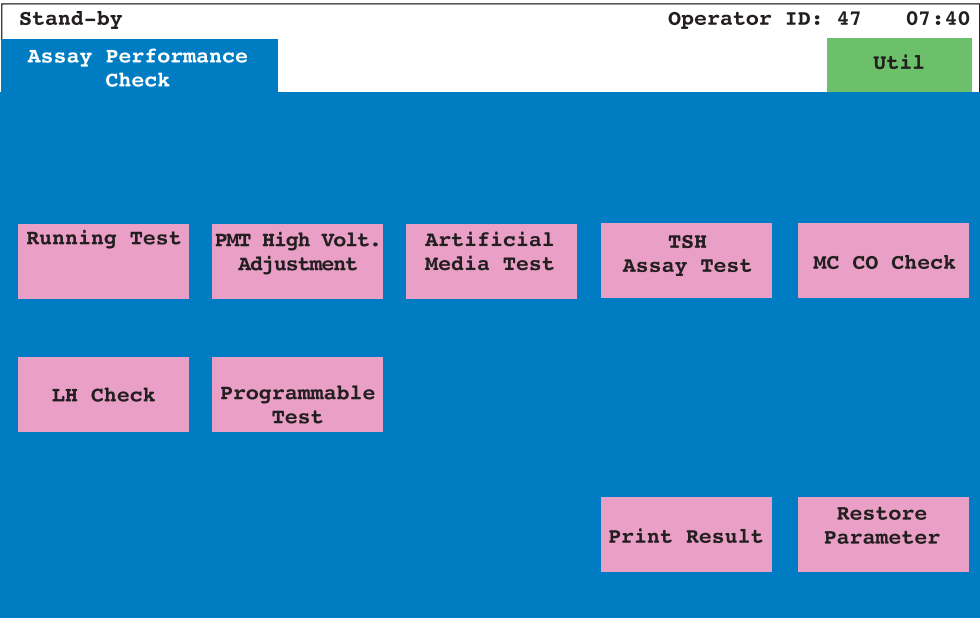
# 7.37 ASSAY PERFORMANCE CHECK Screen

## Introduction

The ASSAY PERFORMANCE CHECK screen is reserved for use by Roche Diagnostics service personnel. It is used to perform various service checks on the analyzer. There is no need to use this screen unless specifically directed to do so by Roche Diagnostics Service or Technical Support.

## ASSAY PERFORMANCE CHECK Screen

An example of the ASSAY PERFORMANCE CHECK screen is shown below.



## 7.38 AUTOMATIC ADJUSTMENT Screen

### Introduction

The AUTOMATIC ADJUSTMENT screen is reserved for use by Roche Diagnostics service personnel. It is used to perform automatic adjustment for the components on the analyzer.



*DO NOT attempt to use this screen unless specifically directed to do so by Roche Diagnostics Service or Technical Support. Misuse of this screen causes movement errors!*



### AUTOMATIC ADJUSTMENT Screen

An example of the AUTOMATIC ADJUSTMENT screen is shown below.

Stand-by		Operator ID: 47 07:40		
Automatic Adjustment		Util		
Gripper-X/Y Tip X:4 Y-3	Gripper-X/Y Tip X:2	Gripper-X/Y Cup Left Y2	Gripper-X/Y Sipping X:7 Y3	Gripper-X/Y Incubator Y3
Gripper-X/Y P. Stn. Tip 1 X:11 Y0	Gripper-X/Y P. Stn. Cup X:10 Y-6	<b>Red Button:</b> Failure to adjust automatically. Try again, after confirming tips/cups.  <b>Yellow Button:</b> The position was on mechanical limits. Adjust it manually.		
Gripper-Z Sipping Z4	Gripper-Z P. Stn. Cup Z-5			
Preparation/ Adjustment				
Gripper All Positions	Tray	Incubator/ Aspiration Stn	Pipetting Station	Gripper-Z

## 7.39 MECHANISM CHECK Screen

### Introduction

The MECHANISM CHECK screen is reserved for use by Roche Diagnostics service personnel. It is mainly used to check the movements or actions of certain components of the analyzer. Touching each button on the screen brings up a pop-up window specific for the check. The check is initiated by touching . Close the window and initiate no action by touching .



*Because there are certain instructions, cup/tip placements, etc., that are specific to each check, DO NOT attempt any check unless you are speaking with Roche Diagnostics Service or Technical Support.*

There is no need to use this screen unless specifically directed to do so by Roche Diagnostics Service or Technical Support.

### MECHANISM CHECK Screen

An example of the MECHANISM CHECK screen for the disk system is shown below.

Stand-by		Operator ID: 47			07:40
Mechanism Check		Util			
Reagent Cap Open/Close M.	Microparticle Mixing	Magnet Up/Down	Waste Tray Shaking	Sample BC Scanning	
Bar Code Card Reading	Reagent Pack BC Scanning	Gripper Quick Check	Gripper Rep. Check	Rgt. Pipetting Cycle	
S/R Probe/ Gripper Check	Sipper	S/R Probe LLD			

# 7.39 MECHANISM CHECK Screen

An example of the MECHANISM CHECK screen for the rack system is shown below.

Stand-by		Operator ID: 47		07:40	
Mechanism Check		Util			
Reagent Cap Open/Close M.		Microparticle Mixing		Magnet Up/Down	
Waste Tray Shaking					
Bar Code Card Reading		Reagent Pack BC Scanning		Gripper Quick Check	
Gripper Rep. Check		Rgt. Pipetting Cycle			
S/R Probe/ Gripper Check		Sipper		S/R Probe LLD	
Sampler Check					

# 7.40 SERVICE Screen

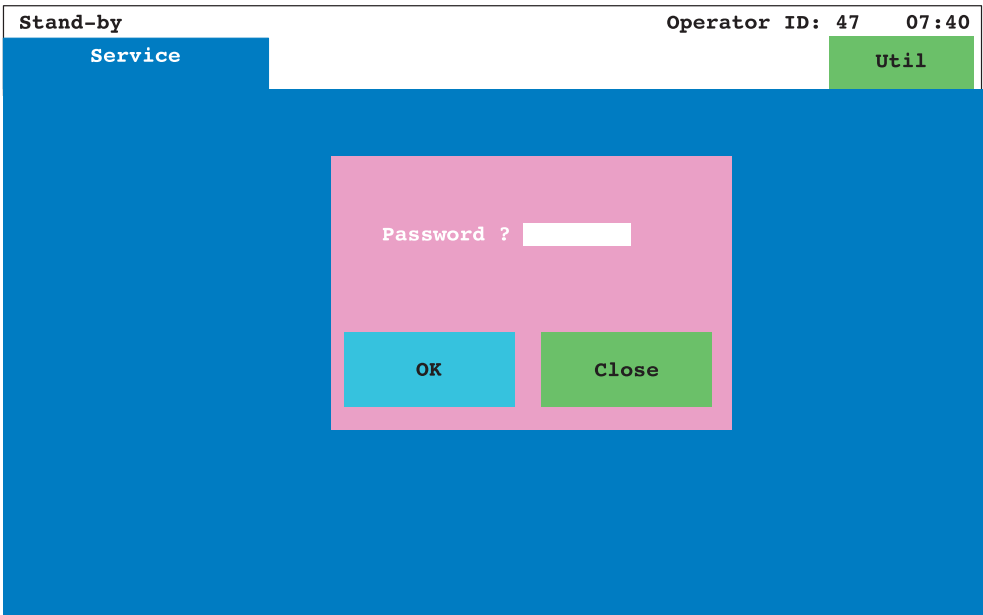
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## Introduction

The SERVICE screen is reserved for use by Roche Diagnostics service personnel. It is password protected. You have no access to this screen.

## SERVICE Screen

An example of the SERVICE screen is shown below.





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## Chapter 8

# Reports

## 8.1 Overview

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### Introduction

Several reports or lists are generated from the Roche Diagnostics Elecsys 2010 Immunoassay analyzer. This chapter contains examples of the available reports and briefly discusses their content and use.

### Report Table

The table below lists the reports available and page number where an example of each report is included.

Report Name (Printout)	Request from this screen or pop-up window	Page Number
Inventory	INVENTORY	8-3
Work List	ORDERS	8-5
Test Results	RESULTS or 'Document Setup'	8-8
QC Results	QC	8-12
Status	STATUS	8-14
Results	---	8-16
Control Definition	'Control Definition'	8-19
Calibration Data	CALIBRATION DATA or 'Calibration Data Details'	8-22
Test Conditions	TEST CONDITIONS or 'Test Conditions Details'	8-36
Message History	'Print Message History'	8-38

## 8.2 Inventory Report

### Introduction

The Inventory report lists the current inventory of reagent packs, cups, tips and other consumables currently on the analyzer.

### How to Print the Inventory Report

Print the Inventory report by pressing  while in the INVENTORY screen.

### Example of the Inventory Report

An example of the Inventory report is shown below.

Inventory		Operator ID: 10		04/08/1998 13:40	
Disk Pos.	Test Code	Test No.	Lot No.	Tests Left	Calib.
2	T-UP	4	192952	172	C
3	FT4	3	193472	173	
4	FT3	6	193370	174	
5	T4	2	190764	163	
6	T3	5	192875	164	
7	TNTSTAT	20	193592	60	
8	CKMBSTAT	21	192915	61	CR
9	HCGSTAT	17	193367	54	
12	TSH	1	192951	35	
15	TSH	1	192951	200	
17	Dil Uni	0	192999	16	
Assay cups		:	27		
Assay tips		:	58		
System reagent		Set 1 :	67 %		
		Set 2 :	56 %		
PC lot no.		Set 1 :	123456		
		Set 2 :	254136		

### Explanation of the Inventory Report

The following is a description of the fields on the Inventory report.

#### Disk Pos.

The reagent disk position of the reagent pack. The report is sorted by disk position number.

#### Test Code

The test abbreviation assigned to the assay.

#### Test No.

The designated test number of the assay. This number is encoded in the reagent bar code, but can be changed in the 'Test Conditions Details' pop-up window (UTIL folder).

## 8.2 Inventory Report

---

**Lot No.**

The lot number of the reagent pack.

**Tests Left**

The number of tests remaining in the reagent pack.

**Calib.**

A "CR" or "C" appears in this field if a calibration is required or manually requested for the reagent pack. A corresponding "CR" or "C" appears on the appropriate test button in the INVENTORY screen.

**Assay cups**

**Assay tips**

The number of cups and tips remaining are listed here.

**System reagent Set 1/Set 2**

The percentage of ProCell and CleanCell remaining in each bottle set is listed here.

**PC lot no. Set 1/Set 2**

The lot number of ProCell in use in each bottle set. This number is entered in the 'System Reagent Details' pop-up window/INVENTORY screen.

## 8.3 Work List

### Introduction

For the disk system, the Work List lists the calibrators, controls and samples currently loaded on the sample disk, as well as the tests selected. This list also contains test selections downloaded from the host for assays not currently loaded on the analyzer.

For the rack system, the Work List lists the calibrators, controls and samples (and their test selections) currently loaded on the sample racks scanned by the bar code reader. This list also contains test selections downloaded from the host for assays not currently loaded on the analyzer.

### How to Print the Work List

Print the Work List by pressing  while in the ORDERS screen.

### Example of the Work List

An example of the Work List for the disk system is shown below.

Work List		Operator ID: 10		04/08/1998 13:40	
-----					
ID	Pos.	Seq.	Vol.	Type	Selected Tests
-----		-----		-----	
Cal 1	0-	1	11	15 Calibrator	FT4
Cal 2	0-	2	12	15 Calibrator	FT4
Cal 1	0-	3	13	50 Calibrator	TSH
Cal 2	0-	4	14	50 Calibrator	TSH
Cal 1	0-	5	15	15 Calibrator	T4
Cal 2	0-	6	16	15 Calibrator	T4
PC U1	0-	7	17	80 Control	FT4,TSH,T4
PC U2	0-	8	18	80 Control	FT4,TSH,T4
00449	0-	9	19	15 Sample	FT4
000024	0-	10	20	65 Sample	TSH(D=10),T4
004893	0-	11	21	80 Sample	FT4,TSH,T4
003822	0-	12	22	80 Sample	FT4,TSH,T4
003828	0-	13	24	80 Sample	FT4,TSH,T4
002955	0-	14	25	30 Sample	TNTSTAT,CKMBSTAT
002884	0-	15	26	30 Sample	TNTSTAT,CKMBSTAT
Rgt packs required : TSH ,FT4 ,T4 ,TNTSTAT ,CKMBSTAT					
Tips required : 70					
Cups required : 34					

## 8.3 Work List

An example of the Work List for the rack system is shown below.

Work List	Operator ID: 10	04/08/1998 13:40
ID	Rack-Pos. Seq. Vol. Type	Selected Tests
00449	00022 - 1 19 15 Sample	FT4
000024	00022 - 2 20 65 Sample	TSH(D=10),T4
004893	00022 - 3 21 80 Sample	FT4,TSH,T4
003822	00022 - 4 22 80 Sample	FT4,TSH,T4
003828	00022 - 5 24 80 Sample	FT4,TSH,T4
002955	00023 - 1 25 30 Sample	TNTSTAT,CKMBSTAT
002884	00023 - 2 26 30 Sample	TNTSTAT,CKMBSTAT

### Explanation of the Work List

The following is a description of the fields on the Work List.

#### ID

The identification number or abbreviation of the sample, calibrator or control.



#### Pos.

The sample disk number and position occupied by the sample.



#### Rack-Pos.

The sample rack ID and position occupied by the sample.

#### Seq.

The sequence number of the sample, calibrator or control.

#### Vol.

The amount of sample required (in µl) based on the tests requested and DOES NOT include the dead volume of the container.

#### Type

The sample type identifier. Identifiers are: Calibrator, Control, Sample or STAT.

#### Selected Tests

The tests selected for the sample are listed here. If a dilution is requested for an assay, it is also listed here.



#### Rgt packs required

The reagent packs required to perform the requested tests.

## 8.3 Work List

---



### **Tips required**

The total number of assay tips required to perform the requested tests.



### **Cups required**



The total number of assay cups required to perform the requested tests.




## 8.4 Test Results Report

### Introduction

The Test Results report lists results for a specific sample or samples. This report is identical in appearance to the Results report. You can designate to have single results per page or multiple results per page. This is determined in the PRINTOUT CONFIGURATION screen.

### How to Print the Test Results Report

Print a Test Results report by touching the  button on the RESULTS screen. Select the sequence range of samples you want to print. Then touch  on the 'Document Setup' pop-up window.

If you wish to only print a report for a single sample, then you must identify the sample in the Sample ID field by either 1) touching the Sample ID field and entering the desired sample ID or 2) with the cursor in the Sample ID or Sequence No. field, using the  or  keys to search for the desired sample. After locating the sample, press  to print the report.



*The screen is updated as the result is printed – it goes to the next sample, or if there are no more results; blank fields are displayed.*

### Example of the Test Results Report

An example of a single Test Results report for the disk system is shown below.

Test Results		Operator ID: 10		04/08/1998 13:40	
-----					
Sample ID	: 120018	Seq No.	: 45	Documented	
Disk - Pos.	: 0- 9	Sampling Date	: 04/08/1998 11:29		
Test Code	Result	Unit	Dil.	Exp. Values	Note Ready Flag
-----					
T4	NoValue ug/dl		[	5.000- 11.50]	11:47 45S
HCGSTAT	426.46 mIU/ml		[	0.00- 5.00]	11:48 49
Flags : 45 = Abnormal aspiration					
49 = Above expected value range					
S = System Block					



## 8.4 Test Results Report

An example of a multiple Test Results report for the disk system is shown below.

Test Results		Operator ID: 10		04/08/1998 13:40	
-----					
Sample ID	: 000018	Seq No.	: 44	Documented	
Disk - Pos.	: 0- 8	Sampling Date	: 04/08/1998 11:30		
Test Code	Result	Unit	Dil.	Exp. Values	Note Ready Flag
-----					
TSH	< 0.005 uIU/ml		[	0.230- 3.80]	11:49 46
Flags : 46 = Potential carryover					
Sample ID	: 120018	Seq No.	: 45	Documented	
Disk - Pos.	: 0- 9	Sampling Date	: 04/08/1998 11:29		
Test Code	Result	Unit	Dil.	Exp. Values	Note Ready Flag
-----					
T4	NoValue ug/dl		[	5.000- 11.50]	11:47 45S
HCGSTAT	426.46 mIU/ml		[	0.00- 5.00]	11:48 49
Flags : 45 = Abnormal aspiration					
49 = Above expected value range					
S = System Block					
Sample ID	: 120156	Seq No.	: 46	Documented	
Disk - Pos.	: 0- 10	Sampling Date	: 04/08/1998 11:30		
Test Code	Result	Unit	Dil.	Exp. Values	Note Ready Flag
-----					
T4	7.52 ug/dl		[	5.000- 11.50]	11:46
HCG	211.39 mIU/ml		[	0.00- 5.00]	11:47 49
Flags : 49 = Above expected value range					

An example of a single Test Results report for the rack system is shown below.

Test Results		Operator ID: 10		04/08/1998 13:40	
-----					
Sample ID	: 120018	Seq No.	: 4000	Documented	
Rack ID - Pos.	: 00005- 5	Sampling Date	: 04/08/1998 11:29		
Test Code	Result	Unit	Dil.	Exp. Values	Note Ready Flag
-----					
T4	NoValue ug/dl		[	5.000- 11.50]	11:47 45S
HCGSTAT	426.46 mIU/ml		[	0.00- 5.00]	11:48 49
Flags : 45 = Abnormal aspiration					
49 = Above expected value range					
S = System Block					

## 8.4 Test Results Report

An example of a multiple Test Results report for the rack system is shown below.

Test Results			Operator ID: 10		04/08/1998 13:40	
-----						
Sample ID	:	000018	P	Seq No.	:	44 Documented
Rack ID - Pos.	:	00010 - 5		Sampling Date	:	04/08/1998 11:30
Test Code	Result	Unit	Dil.	Exp. Values	Note	Ready Flag
-----						
TSH	<	0.005 uIU/ml	[	0.230- 3.80]		11:49 46
Flags : 46 = Potential carryover						
Sample ID	:	120018		Seq No.	:	45 Documented
Rack ID - Pos.	:	00010 - 4		Sampling Date	:	04/08/1998 11:29
Test Code	Result	Unit	Dil.	Exp. Values	Note	Ready Flag
-----						
T4	NoValue	ug/dl	[	5.000- 11.50]		11:47 45S
HCGSTAT	426.46	mIU/ml	[	0.00- 5.00]		11:48 49
Flags : 45 = Abnormal aspiration						
49 = Above expected value range						
S = System Block						
Sample ID	:	120156		Seq No.	:	46 Documented
Rack ID - Pos.	:	00010 - 3		Sampling Date	:	04/08/1998 11:27
Test Code	Result	Unit	Dil.	Exp. Values	Note	Ready Flag
-----						
T4	7.52	ug/dl	[	5.000- 11.50]		11:46
HCGSTAT	211.39	mIU/ml	[	0.00- 5.00]		11:47 49
Flags : 49 = Above expected value range						

### Explanation of the Test Results Report

The following is a description of the fields on the Test Results report.

#### Sample ID

The identification number of the sample.

#### P

Samples that were designated as pre-diluted (i.e., manually diluted) in the ORDERS screen are noted with a "P" that appears at the end of the Sample ID field.



#### Disk - Pos.

The sample disk number and position occupied by the sample.



#### Rack ID - Pos.

The rack ID number and position occupied by the sample.

#### Seq No.

The sequence number assigned to the sample.

## 8.4 Test Results Report

---

### **Documented**

This word appears if the sample was previously documented. This word is missing from reports that are documented for the first time.

### **Sampling Date**

The time and date when the sample in question was sampled.

### **Test Code**

The test abbreviation assigned to the assay.

### **Result**

The test result.

### **Unit**

The unit of measure. A primary unit is encoded in the reagent bar code. If available, another unit can be selected in the 'Test Conditions Details' pop-up window (UTIL folder). If you change the unit of measure after results have printed, the software does not recalculate the result based on the new unit.

### **Dil.**

The dilution factor. If no dilution was selected in the 'Dilution Factor' pop-up window, this field is blank.

### **Exp. Value**

The expected values for the assay are printed if the "Expected Values Check" feature is ON. The "Expected Values Check" is found in the 'Test Conditions Details' pop-up window (UTIL folder). The expected values are encoded in the reagent bar code; however, they can be changed in the 'Test Conditions Details' pop-up window (UTIL folder).

### **Note**

A result message that is displayed if a predefined result condition exists. These messages are set in the software and are not user-definable.

The messages are "reac.", "n-reac." and "border." They are limited to qualitative assays. This note is not sent to the host.

### **Ready**

The time when the sample test results were completed.

### **Flag**

Any flags generated by the system during result measurement. A list of data flags and their descriptions is found in Chapter 2, Data Alarms – *User's Guide*.

## 8.5 QC Results Report

### Introduction

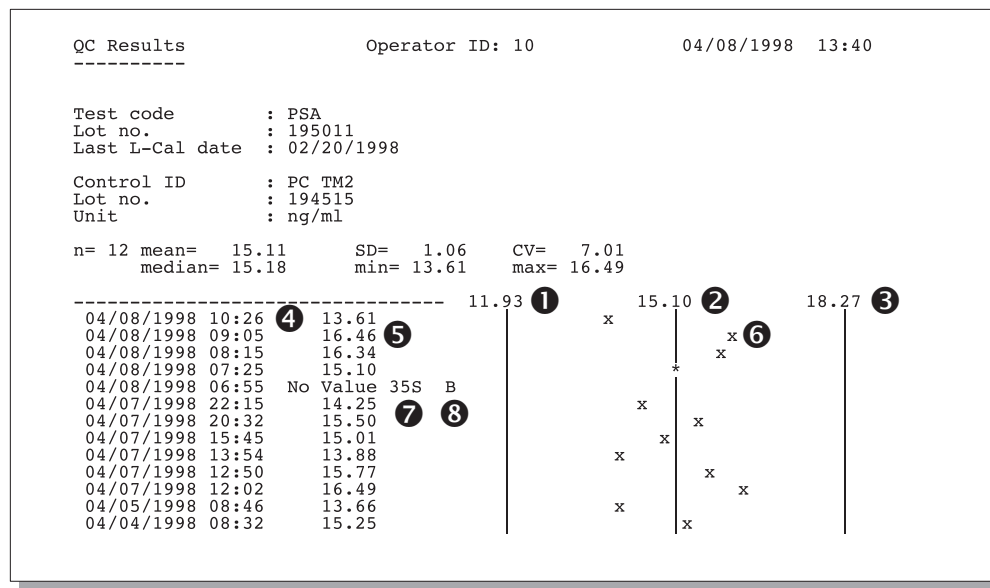
The QC Results report provides a list of a test code's control values for the selected control. The concentrations are shown graphically relative to the minimum value, target value and maximum value for the control. Statistics for the control are listed above the graphic representation.

### How to Print the QC Results Report

Print the QC Results report by pressing  while in the QC screen.

### Example of the QC Results Report

An example of the QC Results report is shown below.



### Explanation of the QC Results Report

The following is a description of the fields on the QC Results report.

#### Test code

The test abbreviation assigned to the selected test.

#### Lot no.

The lot number of the selected test.

## 8.5 QC Results Report

---

**Last L-Cal date****Last R-Cal date**

The date of the assay's last valid calibration for the lot of reagent.

**Control ID**

The control test code.

**Lot no.**

The lot number of the selected control level.

**Unit**

The unit of measure for the selected test. The unit of measure is selected in the TEST CONDITIONS screen (UTIL folder).

**n**

The number of control results for the chart (assay/control combination). You must have at least five results to generate statistics. Blocked values are not included in the statistics.

**mean**

The mean value of all control results is indicated.

**SD**

This field displays the standard deviation.

**CV**

The coefficient of variation is displayed in this field.

**median**

The median of the control results is displayed here.

**min/max**

Displays the minimum and maximum control result of all results on the chart.

- ❶ The lower limit of the control range.
- ❷ The target value of the control.
- ❸ The upper limit of the control range.
- ❹ The date and time the control result was measured.
- ❺ The control result.
- ❻ The control result displayed graphically as an "x." An asterisk indicates that the values falls exactly on the minimum, target or maximum value.
- ❼ Any data flags that occurred at the same time of the control result.
- ❽ If a control result is blocked, a "B" appears here.

## 8.6 Status Report

### Introduction

The Status report provides a list of the current status of all the samples on the sample disk or in racks that have been scanned by the bar code reader.

### How to Print the Status Report

Print the Status report by pressing  while in the STATUS screen.

### Example of the Status Report

An example of the Status report for the disk system is shown below.

Status	Operator ID: 10			04/08/1998 09:56	
-----					
ID	Pos.	Seq.	Type	Status	Ready Time
-----	-----	-----	-----	-----	-----
Cal 1	0- 1	11	Calibrator	Removable	09:46
Cal 2	0- 2	12	Calibrator	Removable	09:48
Cal 1	0- 3	13	Calibrator	Removable	09:52
Cal 2	0- 4	14	Calibrator	Removable	09:55
Cal 1	0- 5	15	Calibrator	Active Sample	
Cal 2	0- 6	16	Calibrator	Occupied	
PC U1	0- 7	17	Control	Occupied	
PC U2	0- 8	18	Control	Occupied	
00449	0- 9	19	Sample	Occupied	
000024	0-10	20	Sample	Occupied	
004893	0-11	21	Sample	Occupied	
003822	0-12	22	Sample	Occupied	
003828	0-13	24	Sample	Occupied	
002955	0-14	25	Sample	Occupied	
002884	0-15	26	Sample	Occupied	
Empty Positions : 0-16, 0-17, 0-18, 0-19, 0-20, 0-21, 0-22, 0-23,0-24,					
0-25, 0-26, 0-26, 0-27, 0-28, 0-29, 0-30					

An example of the Status report for the rack system is shown below.

Status	Operator ID: 10			04/08/1998 09:56		
-----						
ID	Rack-Pos.	Seq.	Type	Status	Ready	
-----	-----	-----	-----	-----	-----	
Cal 1	00012 - 1	4271	Calibrator	Active Sample		
Cal 2	00012 - 2	4272	Calibrator	Occupied		
PC U1	00012 - 3	4273	Control	Occupied		
PC U2	00012 - 4	4274	Control	Occupied		
Cal 1	00011 - 1	4266	Calibrator	Complete	00:00	
Cal 2	00011 - 2	4267	Calibrator	Complete	00:00	
Cal 1	00011 - 3	4268	Calibrator	Complete	00:00	
Cal 2	00011 - 4	4269	Calibrator	Complete	00:00	
004499	00010 - 1	4270	Sample	Complete	07:30	
000024	00010 - 2	4261	Sample	Complete	07:30	
004893	00010 - 3	4262	Sample	Complete	07:31	
003822	00010 - 4	4263	Sample	Complete	07:32	
003828	00010 - 5	4264	Sample	Complete	07:34	
002884	00010 - 1	4265	Sample	Complete	07:23	
002995	00010 - 2	4256	Sample	Complete	07:24	
003697	00010 - 3	4257	Sample	Complete	07:06	
003158	00010 - 4	4258	Sample	Complete	07:25	
006897	00010 - 5	4259	Sample	Complete	07:20	
005446	00010 - 1	4260	Sample	Complete	07:20	
005444	00010 - 2	4253	Sample	Complete	07:21	
009687	00010 - 3	4254	Sample	Complete	07:22	
002222	00010 - 4	4255	Sample	Complete	07:34	

## 8.6 Status Report

### Explanation of the Status Report

The following is a description of the fields on the Status report.

#### **ID**

The identification number or abbreviation.



#### **Pos.**

The current sample disk number and position occupied by the sample.



#### **Rack-Pos.**

The current rack ID and position occupied by the sample.

#### **Seq.**

The sequence number assigned to the sample.

#### **Type**

The sample type identifier. Identifiers are: Calibrator, Control, Sample or STAT.

#### **Status**



The sample status. Status types that appear on the disk report are:

- Occupied
- Active Sample
- In process
- Incomplete
- Complete
- Removable
- Stop
- STAT.



Status types that appear on the rack report are:

- Occupied
- Active Sample
- In process
- Incomplete
- Complete
- STAT.



#### **Ready Time**

The time when the disk sample was completed.



#### **Ready**

The time when the rack sample was completed.



#### **Empty Positions**

A list of the empty positions on the sample disk.

## 8.7 Results Report

---

### Introduction

The Results report is a real time printout of sample results. This report is only available if automatic options are selected and document option is printout or print/upload in the DOCUMENTATION SETUP screen (UTIL folder).

If in the PRINTOUT CONFIGURATION screen you select "single," then one patient report prints per page. If you select "multiple," then as many patient reports as possible print per page.

### How to Print the Results Report

If automatic options are ON and printout or print/upload is the document option, reports print when all of the sample's results are ready. You only need to verify your printer is on-line.

### Example of the Results Report

An example of the single Results report for the disk system is shown below.

```
Results                      Operator ID: 10                04/08/1998 13:40
-----
Sample ID      : 120018                P Seq No.      : 45
Disk - Pos.    : 0- 9                  Sampling Date   : 04/08/1998 11:29

Test Code      Result      Unit      Dil.   Exp. Values      Note      Ready Flag
-----
T4             NoValue ug/dl          [ 5.000- 11.50]          11:47 45S
HCGSTAT        426.46 mIU/ml      [ 0.00- 5.00]          11:48 49

Flags : 45 = Abnormal aspiration
       49 = Above expected value range
       S = System Block
```



## 8.7 Result Report

An example of the single Results report for the rack system is shown below.

Results		Operator ID: 10		04/08/1998 13:40	
-----					
Sample ID : 120018		Seq No. : 2566			
Rack ID - Pos. : 00054 - 3		Sampling Date : 04/08/1998 11:29			
Test Code	Result	Unit	Dil.	Exp. Values	Note Ready Flag
-----					
T4	NoValue	ug/dl	[	5.000- 11.50]	11:47 45S
HCGSTAT	426.46	mIU/ml	[	0.00- 5.00]	11:48 49
Flags : 45 = Abnormal aspiration					
49 = Above expected value range					
S = System Block					

### Explanation of the Results Report

The following is a description of the fields on the Results report.

#### Sample ID

The identification number of the sample.

#### P

Samples that were designated as pre-diluted (i.e., manually diluted) in the ORDERS screen are noted with a "P" that appears at the end of the Sample ID field.



#### Disk - Pos.

The sample disk number and position occupied by the sample.



#### Rack ID - Pos.

The rack ID and position occupied by the sample.

#### Seq No.

The sequence number assigned to the sample.

#### Sampling Date

The time and date when the sample in question was sampled.

#### Test Code

The test abbreviation assigned to the assay.

#### Result

The test result.

## 8.7 Result Report

---

### **Unit**

The unit of measure. A primary unit is encoded in the reagent bar code. If available, another unit can be selected in the 'Test Conditions Details' pop-up window (UTIL folder).

### **Dil.**

The dilution factor. If no dilution was selected in the 'Dilution Factor' pop-up window, this field is blank.

### **Exp. Value**

The expected values for the assay. These values are encoded in the reagent bar code; however, they can be changed in the 'Test Conditions Details' pop-up window (UTIL folder).

### **Note**

A result message that is displayed if a predefined result condition exists. These messages are set in the software and are not user-definable.

The messages are "reac.", "n-reac." and "border". They are limited to qualitative assays. This note is not sent to the host.

### **Ready**

The time when the sample test results were completed.

### **Flag**

Any flags generated by the system during result measurement. A list of data flags and their descriptions is found in Chapter 2, Data Alarms – *User's Guide*.

## 8.8 Control Definition Report

### Introduction

The Control Definition report is a list of all the assays defined for a particular level and lot of control. Each assay, its unit, target value and target range appear.

### How to Print the Calibration Data Report

Touch the desired button on the 'Control Definition' pop-up window and press .

### Example of the Control Definition Report

An example of the Control Definition report is shown below.

Control Definition		Operator ID: 10	01/30/1998 13:46
-----			
Control ID	: PC U1		
Control no.	: 1		
Control lot no.	: 196021		
Exp. date	: 08/1999		
Test no.	: 1		
Test code	: TSH		
Unit	: uIU/ml		
Target value	: 1.67		
Target range	: [ 1.37 - 1.97 ]		
Test no.	: 86		
Test code	: T4		
Unit	: ug/dl		
Target value	: 10.49		
Target range	: [ 8.29 - 12.69 ]		
Test no.	: 3		
Test code	: FT4		
Unit	: ng/dl		
Target value	: 1.32		
Target range	: [ 1.12 - 1.52 ]		
Test no.	: 17		
Test code	: HCGSTAT		
Unit	: mIU/ml		
Target value	: 8.18		
Target range	: [ 5.73 - 10.63 ]		
Test no.	: 31		
Test code	: AFP		
Unit	: IU/ml		
Target value	: 8.93		
Target range	: [ 6.06 - 9.29 ]		
Test no.	: 38		
Test code	: FERR		

Control Definition report for a Roche control

## 8.8 Control Definition Report

Control Definition	Operator ID: 10	01/30/1998 13:46
-----		
Control ID	: Control A	
Control no.	: 64	
Control lot no.	: 123456	
Exp. date	: 10/1999	
Test no.	: 1	
Test code	: TSH	
Unit	: uIU/ml	
Target value	: 1.77	
Target range	: [ 1.77 - 2.07 ]	
Test no.	: 86	
Test code	: T4	
Unit	: ug/dl	
Target value	: 11.49	
Target range	: [ 9.29 - 13.69 ]	
Test no.	: 3	
Test code	: FT4	
Unit	: ng/dl	
Target value	: 2.32	
Target range	: [ 2.12 - 2.52 ]	
Test no.	: 17	
Test code	: HCGSTAT	
Unit	: mIU/ml	
Target value	: 9.18	
Target range	: [ 6.73 - 11.63 ]	
Test no.	: 31	
Test code	: AFP	
Unit	: IU/ml	
Target value	: 9.93	
Target range	: [ 7.06 - 10.29 ]	
Test no.	: 38	
Test code	: FERR	

Control Definition report for a non-Roche control

### Explanation of the Control Definition Report

The following is a description of the fields on the Control Definition report.

#### Control ID

The control test code.

#### Control no.

The assigned control number for the control level. Numbers 1 to 63 are reserved for Roche controls and cannot be changed. Numbers 64 to 99 are for non-Roche controls.

#### Control lot no.

The lot number of the control level.

#### Exp. date

The expiration date of the control level.

#### Test no.

The assigned test number for assay selected for the control.

## 8.8 Control Definition Report

---

### **Test code**

The test code of the assay selected for the control.

### **Unit**

The unit of measure. A primary unit is encoded in the reagent bar code. If available, another unit can be selected in the 'Test Conditions Details' pop-up window (UTIL folder). If you change the unit of measure after results have printed, the software does not recalculate the result based on the new unit.

### **Target value**

The target value for the selected assay for the control level. This value is encoded on the control bar code card or the reagent bar code label. For a non-Roche control or laboratory specific values, this is the value entered in the 'Control Definition Details' pop-up window.

### **Target range**

The target range for the selected assay for the control level. The range is encoded on the control bar code card or the reagent bar code label. For a non-Roche control or laboratory specific values, this is the range resulting from the percentage entered in the 'Control Definition Details' pop-up window.

## 8.9 Calibration Data Report


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### Introduction

The Calibration Data report is generated after calibration (if automatic options are ON and printout or print/upload is the selected document option). It contains information on the specific reagent pack and L-Cal and R-Cal details. Also included in this report are calibration quality criteria. These criteria are used to determine if the calibration is successful.

### How to Print the Calibration Data Report

If automatic options are ON and printout or print/upload is the selected document option, then the report prints automatically after the calibration is completed.

If automatic options are OFF, then you must manually print the report from the CALIBRATION DATA screen. Touch the test button for the desired Calibration Data report and press .

Additionally, you can print the most recent Calibration Data report for an assay at any time after calibration is completed. To print a Calibration Data report for a single assay, touch the test button for the desired assay and press . To print a Calibration Data report for all assays listed on the screen, make sure none of the assays are selected and press .

## 8.9 Calibration Data Report

### Example of the Calibration Data Report

An example of a successful and operator-released assay Calibration Data report for a quantitative assay is shown below and on the next page. The following page shows a successful Calibration Data report for a qualitative assay.

Calibration Data	Operator ID: 10	06/23/1998	09:07
-----			
Lot calibration was successful			
Test code	:	TSH	
Unit	:	uIU/ml	
Lot no. reagent pack	:	194387	
Reagent pack number	:	1665	
Exp. date reagent pack	:	06/1998	
Lot Calibration	:		
Lot calibration date	:	05/13/1998	
Reagent pack no. for Lot Calib.	:	1665	
Lot no. of calibrator	:	194414	
Exp. date calibrator	:	02/1999	
Recommended at	:	06/12/1998	
R. Pack Calibration	:		
Reagent pack calibration date	:	05/13/1998	
Reagent pack no. for R. pack cal.	:	1665	
Lot no. of calibrator	:	194414	
Exp. date calibrator	:	02/1999	
Recommended at	:	05/20/1998	
Calibration Quality Criteria	:		
Missing values	:	-----	
Monotony of curve	:	-----	
Calibration factor	:	1.00	
Minimum signal	:	-----	
Deviation of dup. measurements	:	-----	
System errors	:	-----	
Calibrators	1. Signal	2. Signal	Target Value
1 :	1079	1045	0.000 uIU/ml
2 :	23167	23130	1.48 uIU/ml

Successful L-Cal calibration data report for a quantitative assay

## 8.9 Calibration Data Report

```
Calibration Data          Operator ID: 10          10/06/1998  09:07
-----
Reagent pack calibration questionable
Released as R. pack calib. by operator

Test code                  : TNTSTAT
Unit                       : ng/ml
Lot no. reagent pack       : 196237
Reagent pack number        : 911
Exp. date reagent pack     : 03/1999

Lot Calibration
Lot calibration date       : 09/29/1998
Reagent pack no. for Lot Calib. : 911
Lot no. of calibrator      : 195138
Exp. date calibrator       : 10/1998
Recommended at             : 10/29/1998

R. Pack Calibration
Reagent pack calibration date : 10/06/1998
Reagent pack no. for R. pack cal.: 911
Lot no. of calibrator        : 195138
Exp. date calibrator         : 10/1998
Recommended at               : 10/13/1998

Calibration Quality Criteria
Missing values              --2-----
Monotony of curve           -----
Calibration factor          1.01 -----
Minimum signal              -----
Deviation of dup. measurements -----
System errors               -----

Calibrators    1. Signal    2. Signal    Target Value
1 :             2659        2501        0.100 ng/ml
2 :             0.000        8184        0.740 ng/ml
```

### Questionable R-Cal calibration data report for a quantitative assay

```
Calibration Data          Operator ID: 10          09/23/1998  09:07
-----
Lot calibration was successful

Test code                  : A-HBC
Lot no. reagent pack       : 332233
Reagent pack number        : 2002
Exp. date reagent pack     : 09/1999

Lot Calibration
Lot calibration date       : 09/21/1998
Reagent pack no. for Lot Calib. : 2002
Lot no. of calibrator      : 332233
Exp. date calibrator       : 09/1999
Recommended at             : 10/21/1998

R. Pack Calibration
Reagent pack calibration date : 09/21/1998
Reagent pack no. for R. pack cal.: 2002
Lot no. of calibrator        : 332233
Exp. date calibrator         : 09/1999
Recommended at               : 09/28/1998

Calibration Quality Criteria
Missing values              ----
Slope                       OK
Min/max signal              ----
Minimum acceptable difference OK
Deviation of dup. measurements --
System errors               --

Calibrators    1. Signal    2. Signal
1 :             49877        38862
2 :             608.8        598.4

Cut off: 35415
Borderline area: 1.00 - 1.00
```

### Successful L-Cal calibration data report for a qualitative assay



## 8.9 Calibration Data Report

---

### Explanation of the Calibration Data Report

The following is a description of the fields on an assay Calibration Data report.

#### **date and time**

The date and time that the report was printed appears in the upper right corner.

#### **Lot calibration was successful**

This line by itself states that the calibration was successful and stored in the system as an L-Cal.

#### **Reagent pack calib. was successful**

This line by itself states that the calibration was successful and stored in the system as an R-Cal.

#### **Lot calibration not successful**

##### **Released as R. pack calib. by system**

The calibration was not accepted as an L-Cal, but the system released the calibration as an R-Cal. The reagent pack used for calibration was on the analyzer greater than 24 hours since it was registered. This calibration is only valid for this reagent pack. An L-Cal can only be generated with a reagent pack that has been on the analyzer less than 24 hours since it was registered.

#### **Lot calibration not successful**

##### **Released as R. pack calib. by operator**

The calibration was not accepted as an L-Cal, but the operator released the calibration as an R-Cal. The initial calibration was questionable, but after further review by the operator, it was determined that the calibration could be released. This calibration is only valid for this reagent pack.

#### **R. pack calibration questionable**

##### **Released as R.pack calib by operator**

The attempted R-Cal was questionable and after further review of the calibration quality criteria the calibration was released by the operator. This calibration is only valid for this reagent pack.

#### **This calibration cannot be released**

##### **Valid calibration not available**

An L-Cal was attempted on a new assay or new lot of reagent, but because of failure of calibration quality criteria, the calibration failed. Since this is a new assay or new lot of reagent there is no previous calibration data to which to revert.

#### **Lot calibration not successful**

This line by itself states that the attempted L-Cal was not successful, but a previous valid calibration exists in the system. The system reverted to the previous calibration to calculate sample results.

## 8.9 Calibration Data Report

---

### **Reagent pack calib. not successful**

This line by itself states that the attempted R-Cal was not successful, but a previous valid calibration exists in the system. The system reverted to the previous calibration to calculate sample results.

### **Calib with expired reagent pack**

This message can be combined with any other previously described calibration messages with the exception of "Lot Calibration was successful."

### **Test code**

The test code of the assay being calibrated.

### **Unit**

The unit of measure. A primary unit is encoded in the reagent bar code. If available, another unit can be selected in the 'Test Conditions Details' pop-up window (UTIL folder). This field only appears on a quantitative assay report.

### **Lot no. reagent pack**

The lot number of the reagent pack calibrated.

### **Reagent pack number**

The unique identifier number on the reagent pack. Refer to Section 2.1, INVENTORY Screen, for the location of this number on the reagent bar code label.

### **Exp. date reagent pack**

The expiration date of the reagent pack.

### **Lot Calibration**

#### **Lot calibration date**

The date of the last valid L-Cal for this lot of reagent.

#### **Reagent pack no. for Lot Calib.**

The identifier number of the reagent pack used to generate the L-Cal.

#### **Lot no. of calibrator**

The lot number of the assay's CalSet calibrators that were used in the last valid L-Cal.

#### **Exp. date calibrator**

The expiration date of the assay's CalSet calibrators that were used in the last valid L-Cal.

### **Recommended at**

The date at which the next L-Cal is recommended. This date should primarily be used by high volume reagent users (i.e., the reagent pack is used in less than 7 days.)

## 8.9 Calibration Data Report

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### **R. pack Calibration**

#### **Reagent pack calibration date**

The date of the last valid R-Cal for this lot of reagent.

#### **Reagent pack no. for R. pack cal.**

The identifier number of the reagent pack used to generate the R-Cal.

#### **Lot no. of calibrator**

The lot number of the assay's CalSet calibrators that were used in the last valid R-Cal.

#### **Exp. date calibrator**

The expiration date of the assay's CalSet calibrators that were used in the last valid R-Cal.

### **Recommended at**

The date at which the next R-Cal is recommended. This date should primarily be used by lower volume reagent users (i.e., the reagent pack is **not** used within 7 days.)

## 8.9 Calibration Data Report

### Calibration Quality Criteria

#### Missing values

During calibration curve evaluation, the system checks for the completeness of the curve. Therefore, you must have a minimum of n-1 for all calibrator replicates measured (n = total number of calibrator replicates. For any current Elecsys assay, this number totals four.). If all calibrator replicates were sampled with no errors, this field displays 10 dashes. Refer to the table below.

Field display	n	Would result in a...	Test button color
-----	4	successful calibration	green
1-----	3	questionable calibration	yellow
-1-----	3	questionable calibration	yellow
--2-----	3	questionable calibration	yellow
---2-----	3	questionable calibration	yellow
11-----	2	failed calibration	red
--22-----	2	failed calibration	red
1-2-----	2	failed calibration	red
1--2-----	2	failed calibration	red
-12-----	2	failed calibration	red
-1-2-----	2	failed calibration	red
112-----	1	failed calibration	red
11-2-----	1	failed calibration	red
1-22-----	1	failed calibration	red
-122-----	1	failed calibration	red
1122-----	0	failed calibration	red

There are 10 dashes in this field. You only see information in the first four, representing Cal 1 and Cal 2. Currently, all Elecsys reagents utilize only two calibrators. This field can accommodate up to five calibrators.

Check to see if any alarms occurred during calibration that may have caused the missing replicate. Accept any questionable calibration according to your laboratory policy.

## 8.9 Calibration Data Report

### Monotony of curve

All measured calibrator values must fall in ascending (sandwich or bridging principle) or descending (competition principle) order. This is termed monotony. This field displays five dashes representing up to five calibrators. If either "1" (Cal 1) or "2" (Cal 2) appears in this field, the result is a failed calibration.

Monotony of curve is for **quantitative** assays only.

### Slope

All measured calibrator values must fall in ascending (sandwich or bridging principle) or descending (competition principle) order. If this does not occur, or the slope is less than or greater than the slope encoded in the reagent bar code, the calibration fails. The slope of the assay is listed as "OK" or "Not OK."

Slope is for **quantitative** assays only.

### Calibration factor

The calibration factor is a curve position check compared to the most recent lot calibration. This field displays a number that represents the calibration factor. Calibration factor is only used as a calibration criterion when the system has determined that the calibration cannot be a lot calibration. Refer to the table below.

Calibration factor (x)	Would result in a...	Test button color
$x = 0.8 - 1.2$	successful calibration	green
$x = 0.6 - 0.79$ OR $x = 1.21 - 1.4$	questionable calibration	yellow
$x < 0.6$ OR $x > 1.4$	failed calibration	red

Each lot calibration (L-Cal) utilizes a calibration factor of 1. For all subsequent reagent pack calibrations (R-Cal), a new calibration factor is calculated. The calibration factor is the quotient of the slope of the actual performed calibration and the related stored calibration.

Calibration factor is for **quantitative** assays only.

## 8.9 Calibration Data Report

---

### Minimum signal

The measured signal of the calibrator replicate is below the minimum value. Values are test dependent and are encoded in the reagent bar code. If all calibrator replicates were sampled with no errors, this field displays 10 dashes. Refer to the table below.

Field display	Would result in a...	Test button color
-----	successful calibration	green
1-----	questionable calibration	yellow
-1-----	questionable calibration	yellow
--2-----	questionable calibration	yellow
---2-----	questionable calibration	yellow
11-----	failed calibration	red
--22-----	failed calibration	red
1-2-----	failed calibration	red
1--2-----	failed calibration	red
-12-----	failed calibration	red
-1-2-----	failed calibration	red
112-----	failed calibration	red
11-2-----	failed calibration	red
1-22-----	failed calibration	red
-122-----	failed calibration	red
1122-----	failed calibration	red

There are 10 dashes in this field. You only see information in the first four, representing Cal 1 and Cal 2. Currently, all Elecsys reagents utilize only two calibrators. This field can accommodate up to five calibrators.

Check to see if any alarms occurred during calibration that may have caused a calibrator replicate to have an unacceptable minimum signal. Accept any questionable calibration according to your laboratory policy.

Minimum signal is for **quantitative** assays only.

## 8.9 Calibration Data Report

### Min/max signal

The measured signal of the calibrator should fall between the designated minimum and maximum signal. A minimum and maximum signals are test dependent and encoded in the reagent bar code. If all calibrator replicates were sampled with no errors, this field displays four dashes, representing the calibrators.

This field displays four dashes, representing up to two calibrators measured in duplicate. Refer to the table below.

Field display	Would result in a...	Test button color
----	successful calibration	green
1---	questionable calibration	yellow
-1--	questionable calibration	yellow
--2-	questionable calibration	yellow
---2	questionable calibration	yellow
11--	failed calibration	red
--22	failed calibration	red
1-2-	failed calibration	red
1--2	failed calibration	red
-12-	failed calibration	red
-1-2	failed calibration	red
112-	failed calibration	red
11-2	failed calibration	red
1-22	failed calibration	red
-122	failed calibration	red
1122	failed calibration	red

Check to see if any alarms occurred during calibration that may have caused a calibrator replicate to have an unacceptable min/max signal. Accept any questionable calibration according to your laboratory policy.

Min/max signal is for **qualitative** assays only.

## 8.9 Calibration Data Report

---

### Minimum acceptable difference

The difference between the negative and positive calibrator signal values is less than the allowable value limit. The signals are test dependent and are encoded in the reagent bar code. The minimum acceptable difference is listed as "OK" or "Not OK."

Minimum acceptable difference is for **qualitative** assays only.

### Deviation of dup. measurements

The deviation of duplicate measurements is a check of the signal values for each replicate of a calibrator. If the difference between the duplicate measurements is too great, the appropriate calibrator is flagged. The signal values listed in the **Calibrators** field are the mean value of the duplicate measurements.

This field displays five dashes, representing up to five calibrators. Refer to the table below.

Field display	Would result in a...	Test button color
-----	successful calibration	green
1----	questionable calibration	yellow
-2---	questionable calibration	yellow
12---	failed calibration	red

### System errors

A hardware error occurred during a calibrator measurement. This field displays five dashes representing up to five calibrators. If either 1 (Cal 1) or 2 (Cal 2) appear in this field, the result is a failed calibration.

### Calibrators

#### 1. Signal

The actual signal level of the first replicate measurement of Cal 1 or Cal 2. The mean of the first and second replicate measurements are used in the calculation of the calibration curve.

#### 2. Signal

The actual signal level of the second replicate measurement of Cal 1 or Cal 2. The mean of the first and second replicate measurements are used in the calculation of the calibration curve.



## 8.9 Calibration Data Report

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### Target Value

The target value of the calibrator. This value is encoded in the CalSet calibrator bar code card.

Target Value is for **quantitative** assays only.

### Cutoff

**Qualitative** assays are calibrated by a scaling factor, or the cutoff value. The actual cutoff value is calculated by means of the cutoff formula on the basis of at least one high or low calibrator. Each sample receives a scaled result value, the cutoff value, that allows for the classification of samples being reactive or non-reactive (i.e., the cutoff index is greater than or less than 1).

Cutoff index =  $\frac{\text{measured signal}}{\text{cutoff}}$

### Borderline

For some **qualitative** assays it is possible that in a range around a Cutoff Index = 1, no determination regarding reactive or non-reactive results can be made. This range is called the borderline or borderline area.

Current Elecsys **qualitative** assays have no need for a borderline. Therefore, the upper and lower limit for the borderline area is set to 1; no check is done.

## 8.9 Calibration Data Report

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### Calibration Quality Criteria Table

The following is a table of the quality criteria and their affect on the calibration status on a **quantitative** assay.

Color	Calibration Status	Criteria
green	successful  <i>R-Cal ONLY*</i>	<ul style="list-style-type: none"><li>• no values are missing</li><li>• all values are above the recommended minimum signal level</li><li>• there are no duplicate errors</li><li>• calibration factor is within acceptable range (0.8 - 1.2)</li></ul>
yellow	questionable  <i>R-Cal ONLY*</i>	<ul style="list-style-type: none"><li>• one of either calibrator's duplicate values is missing</li><li>• one of either calibrator's duplicate values is below the recommended minimum signal level</li><li>• one calibrator level was measured with a duplicate error (i.e., the signal difference between the two calibrator determinations is too high)</li><li>• the calibration factor is: 0.6 - 0.79 <i>OR</i> 1.21 - 1.4</li></ul>
red	failed  <i>R-Cal ONLY*</i>	<ul style="list-style-type: none"><li>• two or more of the calibrator's replicate values are missing</li><li>• two or more of the calibrator's replicate values are below the recommended minimum signal level</li><li>• two calibrator levels were measured with a duplicate error (i.e., the signal difference between the two calibrator determinations is too high)</li><li>• failure of monotony (e.g., measured calibrator values were not in either ascending or descending order)</li><li>• calibration factor is out of range (Cal factor &lt; 0.6 <i>OR</i> Cal factor &gt; 1.4)</li></ul>

\* Calibration factor is a criterion used only for R-Cals.

## 8.9 Calibration Data Report

The following is a table of the quality criteria and their affect on the calibration status on a **qualitative** assay.

Color	Calibration Status	Criteria
green	successful	<ul style="list-style-type: none"><li>• no values are missing</li><li>• the slope is within the bar-coded parameters</li><li>• all values are greater than the minimum signal and less than the maximum signal</li><li>• the difference between the negative calibrator and positive calibrator's signal values is greater than the allowable value</li><li>• there are no duplicate errors</li><li>• there are no system errors</li></ul>
yellow	questionable	<ul style="list-style-type: none"><li>• one of either calibrator's duplicate values is missing</li><li>• one of either calibrator's duplicate values is out of the allowable minimum/maximum signal range (i.e., one value is less than the minimum signal or greater than the maximum signal)</li><li>• one calibrator level was measured with a duplicate error (i.e., the signal difference between the two calibrator determinations is too high)</li></ul>
red	failed	<ul style="list-style-type: none"><li>• two or more of the calibrator's replicate values are missing</li><li>• the slope is not within the bar-coded parameters</li><li>• two or more of the calibrator's replicate values are out of the allowable minimum/maximum signal range (i.e., two or more values are less than the minimum signal or greater than the maximum signal)</li><li>• the difference between the negative calibrator and positive calibrator's signal values is less than or equal to the allowable value</li><li>• two calibrator levels were measured with a duplicate error (i.e., the signal difference between the two calibrator determinations is too high)</li></ul>


## 8.10 Test Conditions Report

### Introduction

The Test Conditions report lists the information found in the 'Test Conditions Details' pop-up window. You can either print a report for all test buttons on the TEST CONDITIONS screen, or a report for a single assay. The report is sorted by test number.

### How to Print the Test Conditions Report

If you want a report for all test buttons displayed on the TEST CONDITIONS screen, press  while in the TEST CONDITIONS screen.

If you want a report for a single assay, touch the desired test button on the TEST CONDITIONS screen to access the 'Test Conditions Details' pop-up window. Then, press .

### Example of the Test Conditions Report

An example of a Test Conditions report printed from the TEST CONDITIONS screen and 'Test Conditions Details' pop-up window is shown below.

Test Conditions		Operator ID: 10	04/08/1998 13:40
Test No.	Test Code	Unit	Expected Values
1	TSH	uIU/ml	[ 0.270- 4.20]
2	T4	nmol/l	[ 66.00- 174.0]
3	FT4	pmol/l	[ 13.00- 23.00]
4	T-UP	TBI	[ 0.800- 1.30]
5	T3	nmol/l	[ 1.30- 3.10]
6	FT3	pmol/l	[ 4.00- 7.80]
17	HCGSTAT	mIU/ml	[ 0.500- 5.00]
20	TNTSTAT	ng/ml	[ 0.000- 0.100]
21	CKMBSTAT	ng/ml	[ 0.000- 5.00]

Test Conditions report printed from the TEST CONDITIONS screen

Test Conditions		Operator ID: 10	04/08/1998 13:40
Test No.	Test Code	Unit	Expected Values
1	TSH	uIU/ml	[ 0.270- 4.20]

Test Conditions report printed from the 'Test Conditions Details' pop-up window

## 8.10 Test Conditions Report

---

### Explanation of the Test Conditions Report

The following is a description of the fields on the Test Conditions report.

#### **Test No.**

The test number assigned to the assay. This number is encoded in the reagent bar code. However, you can change the number in the 'Test Conditions Details' pop-up window (UTIL folder).

#### **Test Code**

The test abbreviation assigned to the assay.

#### **Unit**

The unit of measure. A primary unit is encoded in the reagent bar code. If available, another unit can be selected in the 'Test Conditions Details' pop-up window (UTIL folder).

#### **Expected Values**



The expected values for the assay. These values are encoded in the reagent bar code; however, they can be changed in the 'Test Conditions Details' pop-up window (UTIL folder).

# 8.11 Message History Report

## Introduction

The Message History report is a printout of alarm messages currently stored in the system. Up to 200 alarm messages can be printed at a time. A maximum of 200 messages can be stored. After 200 messages are exceeded, messages are overwritten in a first in, first out (FIFO) basis.

## How to Print the Message History Report

Access the 'Print Message History' pop-up window from the MESSAGES screen. In the Up to line field, type the number of alarm messages to print. You can print up to 200 alarms. Press . Then, touch .

## Example of the Message History Report

An example of the Message History report is shown below.

Message History	Operator ID: 10	01/30/1998	13:46
-----			
Message		Date	Time
-----		-----	-----
Bar-coded sample ID error : 50-01-01	3	01/20/1998	08:30
Liquid waste container missing : 24-02-01		01/20/1998	08:19
Liquid waste container full : 24-01-01		01/20/1998	07:39
Abnormal aspiration : 49-01-01	7	01/20/1998	07:35
Sample bar code not read : 38-01-02	25	01/16/1998	14:43
Tray missing on C-Line : 63-02-01		01/16/1998	14:24
Tray missing on A-Line : 61-02-02		01/16/1998	14:21
A-Line: All racks were loaded : 61-02-01		01/16/1998	14:09

## 8.11 Message History Report

---

### Explanation of the Message History Report

The following is a description of the fields on the Message History report.

#### **Message**

The alarm message and alarm number are listed here. Certain alarms also contain an additional number at the end of the field. The exact meaning of this number differs from alarm to alarm. Refer to the specific alarm description in Chapter 3, Instrument Alarms – *User's Guide*.

Certain alarms are specific to one system or another. The shaded box on the preceding page shows three alarms that are specific to the rack system.

#### **Date**

The date the alarm occurred. The most recent alarm is listed first. The remaining alarms are listed in reverse chronological order.

#### **Time**

The time the alarm occurred. The most recent alarm is listed first. The remaining alarms are listed in reverse chronological order.

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## Notes